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EFFECT OF A TRADITIONAL SWEDISH SMOKELESS  
TOBACCO PRODUCT (“SNUS”) ON THE QUIT RATE AMONG  
CIGARETTE SMOKERS WHO WISH TO STOP SMOKING. A  
META-ANALYSIS OF RESULTS FROM TWO RANDOMIZED  
CLINICAL TRIALS

REPORT ON STUDY SM 11-01

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## EXECUTIVE SUMMARY

Meta-analyses have been conducted based on two randomized placebo-controlled, double blind clinical trials, one conducted in the USA, and one in Serbia, of the effect of *ad lib* provision of low nitrosamine snus on quitting smoking. Both studies were of cigarette smokers of a similar age range and similar minimum daily cigarette consumption who did not use smokeless tobacco. The US study involved a 4 week post-randomization period during which the subjects were instructed to use the study products when they felt an urge to smoke, initially without any requirement for complete abstention, a 12 week intervention phase during which subjects were encouraged to quit smoking completely and to use their allocated study product if they felt an urge to smoke, and a follow-up phase of 12 weeks. The Serbian study involved a 24 week post-randomization period during which they subjects were instructed to use the study products to cut down or preferably quit when they felt an urge to smoke, and a 24 week smoking cessation period, during which the subjects were instructed to quit smoking completely by use of the study products. In the Serbian study, subjects who failed to achieve a 50% smoking reduction in weeks 20-24 were withdrawn from the study at week 24.

The primary outcome was continuous smoking cessation (at each of weeks 6 to 28 US and 25 to 48 Serbia, confirmed by exhaled air CO values (<8 ppm at weeks 6, 10, 16 and 28 US and <10 ppm at weeks 30, 42 and 48 Serbia). Five secondary outcomes were defined based on continuous smoking cessation (CO confirmed) for shorter periods or based on being smoke-free (again CO confirmed) at specific weeks.

There were 250 subjects (125 active, 125 placebo) in the US study, and 319 (158 active, 161 placebo) in the Serbian study. The two studies had a similar frequency of males, and the subjects were of similar age and age of starting to smoke. Subjects in Serbia had a higher mean average daily cigarette consumption at baseline, 26.7, than subjects in the USA, 20.4, and a higher Fagerström nicotine dependence score. They were also less likely to have made a previous quit attempt, and very much less likely to have used NRT. There was no evidence in either study of failures of randomization, with the distribution of sex, age, cigarette

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consumption, age of starting to smoke, nicotine dependence score, previous quit attempts and previous use of NRT similar in the active and placebo groups.

None of the outcomes were significantly ( $p<0.05$ ) related to sex, age, age of starting to smoke, nicotine dependence score, previous quit attempts or previous use of NRT. However, in the studies combined, there was a significant ( $p<0.01$ ) tendency for outcome success rates to be greater in lighter smokers.

Only 7 subjects in the USA and 12 in Serbia were successes as defined by the primary outcome. Although the relative success rate exceeded 2 in both the USA (2.50, 95% CI 0.49-12.65) and Serbia (3.06, 0.84-11.08), the meta-analysis estimate (2.83, 1.03-7.75) did not quite reach statistical significance (exact  $p = 0.06$ ). Adjustment for previous cigarette consumption reduced the estimate to 2.10 (0.77-5.76), but the exact  $p$  value remained at 0.06. Although estimated success rates were higher in smokers of 20+ cigarettes per day (RR 6.52, 95% CI 1.18-36.15) than in smokers of 10-19 cigarettes per day (RR 1.15, 0.33-4.01), this heterogeneity was not significant ( $p = 0.10$ ). Nor did success rates vary by the other baseline characteristics studied.

For the combined data, success rates for the five secondary outcomes were typically about twice as high in the active group as in the placebo group. For all the five outcomes, this excess was statistically significant ( $p<0.05$ ). The significant excess for smoking cessation (CO confirmed) in the last 4 weeks of the study period, with success rates of 12.4% for snus vs. 6.6% for placebo (RR 1.86, 95% CI 1.09-3.18), suggests that there is a real advantage to snus in encouraging quitting.

## TABLE OF CONTENTS

INDEX	4
SUMMARY OF THE DESIGNS OF THE TWO STUDIES	6
OBJECTIVES	7
DATA PROVIDED FOR STATISTICAL ANALYSIS	9
POPULATIONS	9
DATA PROCESSING	10
OUTCOMES	10
STATISTICAL METHODS	11
LAYOUT OF STATISTICAL TABLES	16
VARIATION IN OUTCOME BY MAJOR VARIABLES	17
OTHER THAN TREATMENT	
TESTING FOR POSSIBLE FAILURE OF RANDOMIZATION	20
EFFECTS OF TREATMENT	20
DISCUSSION	24
SUMMARY	25
REFERENCES	28

CONFIDENTIAL

TEXT-TABLE 1	Distribution of baseline variables by study	18
TEXT-TABLE 2	Relationship of outcome to average daily cigarette consumption in the year before baseline	19
TEXT-TABLE 3	Testing for possible failure of randomization	20
TEXT-TABLE 4	Meta-analyses of effects of treatment (ITT population)	21
TEXT-TABLE 5	Meta-analyses of effect of treatment on primary outcome by baseline characteristics	23
TEXT-TABLE 6	Meta-analyses of effects of treatment (compliant subjects)	24
TABLE 1	Distribution of Main Outcomes by Confounding Variables by Study	29
TABLE 2	Analysis of Confounding Variables by Study	50
TABLE 3	Analysis of Main Outcomes by Study	58
TABLE 4	Analysis of Main outcomes by Site	64
TABLE 5	Analysis of Main Outcomes by Baseline Characteristics	76
TABLE 6	Analysis of Main Outcomes by Study in Compliant subjects	118
APPENDIX A	Structure of the linked databases	124
APPENDIX B	Listing of individual subject data used in the analysis	147

## SUMMARY OF THE DESIGNS OF THE TWO STUDIES

Two randomized placebo-controlled, double blind clinical trials have been conducted to test whether *ad lib* provision of 0.5 or 1.0 g sachets of low nitrosamine snus, as compared to placebo sachets with no tobacco or nicotine, affects subsequent smoking habits. One (SM 08-01) was conducted in five sites in the USA (Daytona Beach, Austin, Fort Worth, Portland and Evansville). The other (SM 07-01) was conducted in two centres in Belgrade, Serbia. Both studies involved subjects in a similar age range (USA: 25-65 years; Serbia: 20-65 years). Both studies were restricted to subjects who had smoked daily for >1 year, with a similar minimum average consumption level in the preceding month (USA: 9 cigs/day; Serbia: 10 cigs/day), and to subjects who were in good health and who were motivated to change their smoking habits (USA: motivated to quit smoking by a smokeless tobacco (ST) product; Serbia: motivated to substantially reduce or quit smoking). Both studies also effectively excluded current users of ST, in the US by a specific exclusion criterion, in Serbia by ST not being available on the market. Both studies excluded subjects who had used any type of pharmaceutical or other product for smoking cessation in the preceding three months, who had oral conditions that could be worsened by treatment, who abused alcohol or drugs, who had a history of cardiovascular disease, and who were pregnant or lactating. Both studies collected self-reported tobacco status data in a diary completed by the subject, and recorded exhaled carbon monoxide (CO) levels at intervals, as well as conducting a Fagerström test for nicotine dependence.

The US study involved four periods, a screening period of two weeks to evaluate eligibility, a study product test period (weeks 1 to 4 post-randomization) during which the subjects were instructed to use the study products when they felt an urge to smoke, initially without any requirement for complete abstention from cigarettes, an intervention phase (weeks 5 to 16) during which subjects were encouraged to stop smoking completely and to use their allocated study product instead of smoking if they felt an urge to smoke, and a follow-up phase (weeks 17 to 28). Note that the product was supplied only up to week 16, with subjects instructed to cut down on product use during weeks 14 to 16 to avoid too abrupt an ending of nicotine intake. The objectives of the US study included comparison of smoking quit rates measured by complete abstention during weeks 6 to 28, verified by CO <8 ppm (the primary objective),

comparison of verified quit rates measured by complete abstention during weeks 6 to 16, and comparison of verified quit rates specifically at weeks 16 and 28.

The Serbian study involved a baseline visit, a smoking reduction stage (weeks 1 to 24 post-randomization) and a smoking cessation stage (weeks 25 to 48). During the first 24 weeks subjects were instructed to cut down on smoking by taking a sachet of snus when they felt an urge to smoke, though if they still wished to smoke after 20-30 minutes they could do so. Subjects were also informed that although smoking cessation was preferable, the primary objective of the first 24 weeks of the study was smoking reduction. Subjects who failed to achieve smoking reduction at 24 weeks (as judged by a 50% reduction in the self-reported number of cigarettes smoked daily in weeks 20 to 24, and a reduction of at least 1 ppm CO relative to baseline) were withdrawn from the study at week 24. Continuing subjects were instructed to quit smoking completely by use of the sachets. While the primary objective of the Serbian study related to smoking reduction, other objectives related to smoking cessation, both at weeks 12 and 24, and at weeks 36 and 48.

It should be noted that while snus and placebo were only available to week 16 in the US study, snus and placebo were available to the subjects during the whole period post-randomization (weeks 1 to 48) in the Serbian study. This difference arose because, while nicotine replacement therapy (NRT) and various smokeless tobacco products are both readily available to all participants at a cost comparable to cigarettes in the USA, smokeless tobacco is not available in Serbia, and the cost of NRT there is considerably more than that of cigarettes.

## **OBJECTIVES**

Although there are differences between the two studies, there seem to be enough similarities to make it worthwhile to combine the evidence from the studies to allow a more powerful test of whether use of low nitrosamine snus vs placebo sachets affects the rate of quitting smoking. Both studies are relatively small (USA 125 in each group; Serbia 158 snus and 161 placebo), and a meta-analysis of appropriately defined endpoints should allow improved insight into the main hypothesis of interest.

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In deriving endpoints, it seems appropriate to consider the period following when the advice given to subjects concentrated on quitting, i.e. from week 5 in the US study and from week 25 in the Serbian study. To avoid bias, it is also appropriate to base the main analyses on all the subjects randomized initially, so including those withdrawn at week 24 in the Serbian study because they failed to achieve a 50% reduction in the number of cigarettes smoked daily by them, and were assumed not to be going to quit had they continued in the study.

The main purpose of the study is to combine evidence from available randomized, placebo-controlled, double blind clinical trials to test whether use of a low-nitrosamine, Swedish snus product can increase the smoking cessation rate among cigarette smokers motivated to change their smoking habits.

The primary objective of the meta-analysis is to examine if a traditional Swedish low-nitrosamine ST product (“snus”), compared to placebo, can increase the quit rate among cigarette smokers motivated to change their smoking habits, as quantified by continuous, complete smoking cessation over an approximate 20-week period following advice to quit smoking. For the US study, this is defined as complete abstention during weeks 6 to 28 verified by expired air CO less than 8 ppm. For the Serbian study, this is defined as complete abstention during weeks 25 to 48, verified by expired air CO less than 10 ppm.

The secondary objectives of this study are:

- To examine point-prevalence (preceding week) quit rates (biologically confirmed) at the following defined pairs of times in the two studies;
  - weeks 6 USA and week 24 Serbia,
  - week 16 USA and week 36 Serbia,
  - week 28 USA and week 48 Serbia.
- To examine the prevalence of smoke-free subjects (self-reported and confirmed by CO measurement) at weeks 25-28 in the US study and at weeks 45-48 in the Serbian study.

- To examine the prevalence of smoke-free subjects (self-reported and confirmed by CO measurement) at weeks 17-28 in the US study and at weeks 37-48 in the Serbian study.

## **DATA PROVIDED FOR STATISTICAL ANALYSIS**

P N Lee Statistics and Computing Ltd. (PNLSC) were supplied by Swedish Match with electronic data files (SAS) for each of the two studies containing information for each subject randomized. This information included:

Site where the subject attended  
Sex  
Age  
Smoking history  
History of quit attempts and use of cessation aids  
Date at which the subject was randomized  
Whether the subject was randomized to snus or placebo  
Results of the CO Exhaled air test (weeks 0, 6, 10, 16 and 28 for the US study; weeks 0, 2, 6, 12, 18, 24, 30, 36, 42 and 48 for the Serbian study)  
Results of the Fagerström test conducted at baseline  
Self-reported smoking status for each week of the study  
Whether the subject used the study product (snus or placebo) for each week of the study  
Whether the subject completed the study or was withdrawn  
Whether the subject reduced or stopped smoking (Serbian study only, weeks 12, 24, 36 and 48)  
Date of completion or withdrawal

## **POPULATIONS**

Analysis was mainly carried out using the intention-to-treat (ITT) population. This is defined as all eligible subjects who had a baseline evaluation, were randomized to receive one of the study products, and used at least one dose of the assigned product, irrespective of compliance and protocol violations.

Some additional analyses were conducted based on compliant subjects, defined as those who used the product on average at least one day a week in each of weeks 1 to 5 (US) or weeks 1 to 24 (Serbia).

## DATA PROCESSING

The relevant individual subject data were transferred onto two similarly structured linked ROELEE databases, one for each study, to allow for statistical analysis.

[Appendix A](#) gives details of the structure of these databases, and

[Appendix B](#) lists the individual subject data used in the analysis.

The distributions of the variables used in the analysis were compared with output prepared by the study sites to ensure that the transfer had been successful.

## OUTCOMES

For the US study the primary outcome measure is continuous smoking cessation during weeks 6 to 28 inclusive based on diary readings recorded at these weeks confirmed by exhaled air CO values of less than 8 ppm at weeks 6, 10, 16 and 28.

For the Serbian study the primary outcome measure is continuous smoking cessation during weeks 25 to 48 inclusive based on diary readings recorded at those weeks confirmed by CO values from exhaled air of less than 10 ppm at weeks 24, 36 and 48.

Note that, for the US study, the outcomes were based directly on the diary readings and CO values. For the Serbian study the outcomes were based on summaries recorded at the efficacy assessments made at weeks 12, 24, 36 and 48.

Secondary outcome measures are:

1. The point prevalence of smoke-free subjects (confirmed by CO measurement) at week 6 in the US study and at week 24 in the Serbian study.
2. The point prevalence of smoke-free subjects (confirmed by CO measurement) at week 16 in the US study and at week 36 in the Serbian study.
3. The point prevalence of smoke-free subjects (confirmed by CO measurement) at week 28 in the US study and at week 48 in the Serbian study.

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4. Continuous smoking cessation (confirmed by CO measurement) at weeks 25-28 in the US study and at weeks 45-48 in the Serbian study.
5. Continuous smoking cessation (confirmed by CO measurement) at weeks 17-28 in the US study and at weeks 37-48 in the Serbian study.

Missing values for smoking status or CO measurement were taken as indicating that the subject smoked on that occasion. The diary readings used had been reviewed at weeks 6, 10, 16 and 28 in the US study, and at weeks 24, 36 and 48 in the Serbian study.

## **STATISTICAL METHODS**

Variables other than study treatment (active or placebo) considered as possibly affecting outcome (“Potential confounding variables”) are the following:

Site where the subject attended (five in the USA, two in Serbia)

Sex

Age

Average cigarettes smoked per day in the year before baseline

Age at starting to smoke

Fagerström nicotine dependence score at baseline

Previous quit attempt

Previous use of NRT

Statistical analyses test for variation in a response by levels of a factor both within each level of a partitioning variable, and also overall, with adjustment for the partitioning variables.

The analyses can be divided into five types:

	<u>Response</u>	<u>Factor</u>	<u>Partitioning variable</u>
1.	Outcome	Potential confounding variable	Study
2.	Potential confounding variable	Study product	Study
3.	Outcome	Study product	Study
4.	Outcome	Study product	Study site
5.	Outcome	Study product	Study, potential confounding variable

Analyses of type 1 give background information on variables other than the study product that might affect outcome. For some variables, e.g. sex, the factor only has two levels. However, for continuous or semi-continuous variables, the factor is categorized to include up to five monotonically increasing levels, based on inspection of the distribution of the variable so as to have approximately equal number of subjects in each category. In this case the analysis includes a test for trend, i.e. for response to increase or decrease with successive levels of the factor variable.

Analysis of type 2 investigates possible failures of randomization. Variables showing differences between snus and placebo that are significant at  $p<0.05$  are considered as partitioning variables in the type 5 analyses, and if none are significant, the analysis is not carried out.

Analyses of types 3 to 5 (the meta-analyses) test for a relationship between study product and outcome, and concern the main hypothesis of interest – the effect of snus on the quit rate. The analyses presented are fixed-effect meta-analyses based on the logit method, as described in e.g. [Fleiss & Gross, 1991](#). Alternative analyses (not shown) using the Mantel-Haenszel method ([Greenland & Robins, 1985](#)) gave very similar results. The intention had been to also conduct random-effect meta-analyses where there was significant ( $p<0.05$ ) evidence of heterogeneity of the relative risk over partitions, but as this never occurred, only

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the fixed-effect methods are described below. For the meta-analyses, the data for each level of the partitioning variable ( $i = 1, 2 \dots s$ ) can be laid out as follows:

<u>Subjects</u>	<u>Active (Snus)</u>	<u>Placebo</u>
Outcome successful (quit smoking)	$A_i$	$B_i$
At risk	$C_i$	$D_i$

The relative risk for level  $i$  is estimated by

$$RR_i = (A_i D_i) / (B_i C_i)$$

and the variance of  $\log_e RR_i$ ,  $V_i$ , is estimated by (Katz et al., 1978)

$$V_i = \text{var} (\log_e RR_i) = 1/A_i + 1/B_i - 1/C_i - 1/D_i$$

The combined fixed-effect estimate of  $\log_e RR$  over the partitions is calculated as an inverse-variance weighted average of the individual estimates. Thus, we have

$$Y_T = \log_e RR_T = \left( \sum_{i=1}^s w_i \log_e RR_i \right) / \sum_{i=1}^s w_i$$

where  $w_i$ , the weight, equals  $1/V_i$ .

Thus the overall estimate  $RR_i$  is given by  $\exp(Y_T)$ .

The variance of  $\log_e RR_T$ ,  $V_T$ , is then estimated by

$$V_T = \text{var} (\log_e RR_T) = 1 / \sum_{i=1}^s w_i$$

A 95% confidence interval for the overall estimate of  $RR_T$  is then given by

$$\exp(Y_T \pm Z \sqrt{V_T})$$

Where  $Z$  is the value of the standard normal distribution corresponding to the 97.5% percentile (i.e. approximately 1.96).

The output from the analyses also includes the results of unstratified and stratified chisquared and exact tests. Inference will always be based upon the exact probabilities where these can be calculated. The chisquared tests have not been Yates' corrected as then the resulting chisquared statistics and probabilities relate directly to the relative risks. It should be noted that due to the small number of cases there will be appreciable differences between the approximate asymptotic probabilities and the exact probabilities. The results of a test of the heterogeneity of the relative risk over the partitions will also be shown, based on taking the statistic

$$Q = \sum_{i=1}^s w_i (Y_i - Y_T)^2$$

as having a chi-squared distribution with  $s-1$  degrees of freedom ([Fleiss & Gross, 1991](#)).

The methods used for the analyses of type 1 are the same as for the meta-analyses, except that the basic data table is changed to:

<u>Subjects</u>	<u>Potential confounding variables</u>			
	<u>Level 1</u>	<u>Level 2</u>	....	<u>Level s</u>
Outcome successful (quit smoking)	$A_1$	$A_2$		$A_s$
At risk	$C_1$	$C_2$		$C_s$

with relative risks expressed compared to a reference level of the confounding variable. Here the analyses also include tests for overall variation between groups and for trend ([Breslow & Day, 1980](#)).

For analyses of type 2, where the potential confounding variable has two levels, the methodology is similar to that for the analyses of types 3, 4 and 5, except that the basic data table is changed to, e.g.

<u>Subjects</u>	<u>Snus</u>	<u>Placebo</u>
Males	A <sub>i</sub>	B <sub>i</sub>
Total	C <sub>i</sub>	D <sub>i</sub>

and the statistic  $(A_i D_i) / (B_i C_i)$  measures the relative frequency of males in the two groups.

For analyses of type 2, where the potential confounding variable is continuous or semi-continuous, comparisons of snus and placebo are carried out using Wilcoxon rank tests ([Conover, 2003](#)) to compare the median response in the two groups. Other descriptive statistics are also presented, such as the mean and standard deviation. For an overall comparison over levels of the partitioning variable, a stratified version of the Wilcoxon rank test is used ([Fry & Lee, 1991](#)).

In the above analyses of continuous or semi-continuous potential confounding variables the following levels are used are used as factors, partitioning variables or trend coefficients:

<u>Potential confounding variable</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>
Age	20-36 (base)	37-45	46-52	53-64	-
Average cigarettes smoked per day in the year before baseline	10-19 (base)	20	21-30	31-60	-
Age of starting to smoke	8-15 (base)	16-17	18-19	20-21	22-53
Fagerström nicotine dependence score at baseline	0-4 (base)	5	6	7	8-10

## LAYOUT OF STATISTICAL TABLES

Where the response variable is outcome and the factor is randomization group, the following statistics are shown for each level of the partitioning variable:

N	Number of subjects with positive outcome
E	Expected number responding if no effect of treatment
N	Number of subjects analyzed
%	Percentage with positive outcome (100 n/N)
Chisq	Chisquared statistic for effect of treatment
ChiP	Chisquared p value
ExP	Exact p value
RR	Relative risk and 95% confidence interval

For the total over partitions, the same statistics are also shown, but the last four (Chisq, ChiP, ExP, RR) relate to the results of stratified analysis. Also shown is:

RRP	p value for the test of heterogeneity of the relative risk over the levels of the partitioning variable
-----	---

The output is similar for other analyses where the response variable has two levels.

Where the factor level has more than two levels, results of statistical tests shown in the column for a particular level relate to the comparison with the base level (where no such results are shown). The results shown in the “Total” column relate to a test of overall variation by level, while the results in the “Trend” column relate to the trend test.

Where the response variable is continuous or semi-continuous and nonparametric rank tests are used, the following statistics are shown:

N	Number of subjects analyzed
Mean	Mean

St.Err	Standard error
St.Dev	Standard deviation
Median	Median
Range	Lowest value: Highest value
Q25:75	25 <sup>th</sup> percentile: 75 <sup>th</sup> percentile
KWS	Kruskal-Wallis statistic
KWP	Kruskal-Wallis p value

For the total over partitions, the Kruskal-Wallis statistics and p values relate to results of stratified analysis. Also shown is:

KWD      Difference between mean rank for the group and the average mean rank, summed over the partitions.

## **VARIATION IN OUTCOME BY MAJOR VARIABLES OTHER THAN TREATMENT**

[Text-Table 1](#) shows the distribution of the potential confounding variables (sex, age, cigarettes per day, age of starting to smoke, Fagerström dependency test score, previous quit attempts and previous use of NRT) by study. No significant ( $p<0.05$ ) differences between study were seen in sex, age or age of starting to smoke. However, significant ( $p<0.001$ ) differences were seen in the other four variables, with subjects in Serbia having a higher average cigarette consumption per day, a higher Fagerström nicotine dependence score, and a lower likelihood of having made a previous quit attempt or having previous exposure to NRT.

[Table 1](#) shows the results of tests for variation in outcome by level of these variables. There was no significant ( $p<0.05$ ) evidence that any outcome varied by sex in either study, or overall. Nor was there any significant ( $p<0.05$ ) evidence of a tendency for any outcome to show an increasing or decreasing trend in relation to age, age of starting to smoke or Fagerström dependency score. However, as shown in [Text-Table 2](#), there was a clear tendency for all the outcomes to show a reducing trend in relation to increasing daily

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TEXT-TABLE 1 Distribution of baseline variables by study<sup>a</sup>

<u>Variable</u>	<u>Level</u>	<u>USA</u>	<u>Serbia</u>	<u>Signif<sup>b</sup></u>	<u>Combined</u>
Sex	Male	98 (39.2%)	123 (38.6%)	NS	221 (38.8%)
	Female	152 (60.8%)	196 (61.4%)		348 (61.2%)
Age	20-36	65 (26.0%)	82 (25.7%)		147 (25.8%)
	37-45	54 (21.6%)	84 (26.3%)		138 (24.3%)
	46-52	62 (24.8%)	84 (26.3%)		146 (25.7%)
	53-64	69 (27.6%)	69 (21.6%)		138 (24.3%)
	Mean	45.04	43.64	NS	44.25
Average cigarettes smoked per day in the year before baseline	10-19	84 (33.6%)	32 (10.0%)		116 (20.4%)
	20	108 (43.2%)	114 (35.7%)		222 (39.0%)
	21-30	45 (18.0%)	112 (35.1%)		157 (27.6%)
	31-60	13 (5.2%)	61 (19.1%)		74 (13.0%)
	Mean	20.40	26.66	+++	23.91
Age of starting to smoke	8-15	77 (30.8%)	54 (16.9%)		131 (23.0%)
	16-17	58 (23.2%)	67 (21.0%)		125 (22.0%)
	18-19	44 (17.6%)	89 (27.9%)		133 (23.4%)
	20-21	33 (13.2%)	59 (18.5%)		92 (16.2%)
	22-53	38 (15.2%)	50 (15.7%)		88 (15.5%)
	Mean	18.39	19.01	NS	18.74
Fagerström nicotine dependence score at baseline	0-4	72 (28.8%)	68 (21.3%)		140 (24.6%)
	5	49 (19.6%)	41 (12.9%)		90 (15.8%)
	6	48 (19.2%)	60 (18.8%)		108 (19.0%)
	7	35 (14.0%)	58 (18.2%)		93 (16.3%)
	8-10	46 (18.4%)	92 (28.8%)		138 (24.3%)
	Mean	5.55	6.17	+++	5.90
Previous quit attempt	Yes	219 (87.6%)	116 (36.4%)	---	335 (58.9%)
	No	31 (12.4%)	203 (63.6%)		234 (41.1%)
Previous exposure to NRT	Yes	126 (50.4%)	3 (0.9%)	---	129 (22.7%)
	No	124 (49.6%)	316 (99.1%)		440 (77.3%)
Number of subjects		250	319		569

<sup>a</sup> The table shows the number of subjects, and the percentage of the study population.

<sup>b</sup> NS p≥0.05; +++ p<0.001 Serbia > USA; --- p<0.001 USA < Serbia.

cigarette consumption. The trend was significant ( $p<0.05$ ) for all the outcomes for the overall data and for Serbia, but only significant for secondary outcomes 1 and 2 for the USA. This may partly reflect the smaller number of heavier smokers in the US study. Relative success rates in smokers of 10-19 cigarettes per day compared to smokers of 31-60 cigarettes per day ranged from 3 to 5 (5.0 for the primary outcome, and 4.8, 3.8, 3.0, 4.0 and 3.2 for secondary outcomes 1 to 5 respectively).

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TEXT-TABLE 2 Relationship of outcome to average daily cigarette consumption in the year before baseline<sup>a</sup>

<u>Outcome</u>	<u>Cigs/day</u>	<u>USA</u> n (%)	<u>Serbia</u> n (%)	<u>Total</u> n (%)
<b>PRIMARY OUTCOME</b>				
Cessation weeks 6-28 (USA)	10-19	4 ( 4.76%)	5 (15.63%)	9 ( 7.76%)
weeks 25-48 (Serbia)	20	3 ( 2.78%)	4 ( 3.51%)	7 ( 3.15%)
	21-30	0 ( 0.00%)	2 ( 1.79%)	2 ( 1.27%)
	31-60	0 ( 0.00%)	1 ( 1.64%)	1 ( 1.35%)
	Trend p <sup>b</sup>	0.1428	0.0075	0.0013
<b>SECONDARY OUTCOMES</b>				
1. Smoke-free week 6 (USA)	10-19	17 (20.24%)	5 (15.63%)	22 (18.97%)
week 24 (Serbia)	20	14 (12.96%)	3 ( 2.63%)	17 ( 7.66%)
	21-30	2 ( 4.44%)	3 ( 2.68%)	5 ( 3.18%)
	31-60	1 ( 7.69%)	1 ( 1.64%)	2 ( 2.70%)
	Trend p <sup>b</sup>	0.0160	0.0197	0.0006
2. Smoke-free week 16 (USA)	10-19	18 (21.43%)	7 (21.88%)	25 (21.55%)
week 36 (Serbia)	20	12 (11.11%)	6 ( 5.26%)	18 ( 8.11%)
	21-30	1 ( 2.22%)	5 ( 4.46%)	6 ( 3.82%)
	31-60	1 ( 7.69%)	3 ( 4.92%)	4 ( 5.41%)
	Trend p <sup>b</sup>	0.0026	0.0274	0.0002
3. Smoke-free week 28 (USA)	10-19	13 (15.48%)	12 (37.50%)	25 (21.55%)
week 48 (Serbia)	20	8 ( 7.41%)	13 (11.40%)	21 ( 9.46%)
	21-30	2 ( 4.44%)	11 ( 9.82%)	13 ( 8.28%)
	31-60	2 (15.38%)	4 ( 6.56%)	6 ( 8.11%)
	Trend p <sup>b</sup>	0.1932	0.0008	0.0003
4. Cessation weeks 25-28 (USA)	10-19	10 (11.90%)	9 (28.13%)	19 (16.38%)
weeks 45-48 (Serbia)	20	7 ( 6.48%)	12 (10.53%)	19 ( 8.56%)
	21-30	2 ( 4.44%)	10 ( 8.93%)	12 ( 7.64%)
	31-60	1 ( 7.69%)	3 ( 4.92%)	4 ( 5.41%)
	Trend p <sup>b</sup>	0.2176	0.0046	0.0018
5. Cessation weeks 17-28 (USA)	10-19	10 (11.90%)	7 (21.88%)	17 (14.66%)
weeks 37-48 (Serbia)	20	6 ( 5.56%)	7 ( 6.14%)	13 ( 5.86%)
	21-30	1 ( 2.22%)	4 ( 3.57%)	5 ( 3.18%)
	31-60	1 ( 7.69%)	3 ( 4.92%)	4 ( 5.41%)
	Trend p	0.1005	0.0138	0.0022

<sup>a</sup> The table shows the number (percentage) of subjects satisfying the criterion for a successful outcome.

<sup>b</sup> Note that trend p is from an exact test; trend p values from chisquared tests were similar.

## TESTING FOR POSSIBLE EFFECTS OF RANDOMIZATION

Based on the results in [Table 2](#), there is no evidence for either study, or overall, of any failure of randomization, with the proportion who were male, who had made a previous quit attempt, and who previously used NRT, and the mean age, cigarette consumption in the year before baseline, age started smoking and Fagerström dependency score similar in the active and placebo groups. The main results are summarized in Text-Table 3.

TEXT-TABLE 3 Testing for possible failure of randomization<sup>a</sup>

	USA		Serbia		Total	
	Active	Placebo	Active	Placebo	Active	Placebo
Sex (% male)	35.2	43.2	37.3	39.8	36.4	41.3
Age (mean)	44.3	45.7	43.3	44.0	43.8	44.8
Cigarettes/day in year before baseline (mean)	20.2	20.6	27.6	25.7	24.3	23.5
Age started smoking (mean)	18.1	18.7	19.2	18.8	18.7	18.8
Fagerström dependency test (mean)	5.53	5.58	6.21	6.14	5.91	5.89
Previous quit attempt (% Yes)	89.6	85.6	36.1	36.6	59.7	58.0
Previous use of NRT (% Yes)	55.2	45.6	0.6	1.2	24.7	20.6
Number of subjects	125	125	158	161	283	286

<sup>a</sup> All tests for differences between active and placebo give p values exceeding 0.1.

## EFFECTS OF TREATMENT

[Table 3](#) shows the results of analyses testing for effects of outcome by site and overall.

In the two studies combined, only 19 subjects were successes as defined by the primary outcome, 7 in US and 12 in Serbia. Although the success rate was higher in the active group in both studies, with the relative risk (i.e. relative success rate) estimate exceeding 2 in both the USA (2.50, 0.49-12.65) and Serbia (3.06, 0.84-11.08), the meta-analysis estimate (2.83, 1.03-7.75) was of borderline statistical significance (exact p = 0.06).

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As shown in Text-Table 4, which summarizes the results from [Table 3](#), all the secondary outcomes showed an advantage to the active group in both studies. Because they involved more total successful outcomes than was the case for the primary outcome, many of the relative success rate estimates are statistically significant at  $p<0.05$ . Indeed, for the results meta-analyzed over study, all five estimates are about 2.0 and statistically significant.

TEXT-TABLE 4      Meta-analyses of effects of treatment (ITT population)

<u>Outcome</u>		<u>USA</u>	<u>Serbia</u>	<u>Total (adjusted for study)</u>
<b>PRIMARY OUTCOME</b>				
Cessation weeks 6-28 (USA) weeks 25-48 (Serbia)	n <sup>a</sup> RR	5/2 2.50 (0.49-12.65)	9/3 3.06 (0.84-11.08)	14/5 2.83 (1.03-7.75)
<b>SECONDARY OUTCOMES</b>				
1. Smoke-free week 6 (USA) week 24 (Serbia)	n <sup>a</sup> RR	23/11 2.09 (1.07-4.10)	9/3 3.06 (0.84-11.08)	32/14 2.27 (1.25-4.12)
2. Smoke-free week 16 (USA) week 36 (Serbia)	n <sup>a</sup> RR	22/10 2.20 (1.09-4.45)	15/6 2.55 (1.01-6.40)	37/16 2.32 (1.33-4.07)
3. Smoke-free week 28 (USA) week 48 (Serbia)	n <sup>a</sup> RR	16/9 1.78 (0.82-3.87)	25/15 1.70 (0.93-3.10)	41/24 1.73 (1.07-2.78)
4. Cessation weeks 25-28 (USA) weeks 45-48 (Serbia)	n <sup>a</sup> RR	13/7 1.86 (0.77-4.50)	22/12 1.87 (0.96-3.64)	35/19 1.86 (1.09-3.18)
5. Cessation weeks 17-28 (USA) weeks 37-48 (Serbia)	n <sup>a</sup> RR	12/6 2.00(0.77-5.16)	15/6 2.55 (1.01-6.40)	27/12 2.27 (1.17-4.39)
Number of subjects	n <sup>b</sup>	125/125	158/161	283/286

<sup>a</sup> The first number shown is the number of successes in the active group, and the second is the number in the placebo group.

<sup>b</sup> The first number shown is the number of subjects in the active group, and the second is the number in the placebo group.

Table 3 also includes results showing that, for all the outcomes, there was no evidence ( $p>0.6$ ) of heterogeneity of the relative success rate estimates by study. As a result (data not shown), random-effects estimates of the overall relative success rate over the two studies were identical to those shown in Table 3 and Text-Table 4.

[Table 4](#) shows the results from analyses adjusted for study site. The overall relative success rate estimates are somewhat lower than those shown in Text-Table 4: primary outcome 2.36 (0.92-6.05); secondary outcomes 1 to 5 in turn 2.02 (1.12-3.64), 2.11 (1.21-3.70), 1.66 (1.03-

2.67), 1.68 (0.98-2.87) and 1.84 (0.95-3.56). However, the conclusion that the increased success rate in the active group is not significant for the primary outcome, but significant for all of the secondary outcomes, remains the same.

Due to the significant difference in the outcomes by smoking intensity and the difference between studies for many of the cofactors, it was decided to examine whether the estimated effect of treatment on outcome changed when each of the cofactors was allowed for in turn.

**Table 5** presents the results of analyses partitioned on:

- a) sex,
- b) age (20-45 vs 46-64),
- c) smoking intensity (whether or not the subjects were light smokers, defined as 10-19 cigarettes per day in the year before baseline),
- d) age started smoking (<18 vs 18+),
- e) nicotine dependence (Fagerström nicotine dependence score 0-6 vs 7+),
- f) previous quit attempts (yes/no) and
- g) previous use of NRT (yes/no).

As the studies varied on many of these cofactors the analyses were also stratified for study. The results are summarized in **Text Table 5**. The resulting relative success rates were somewhat lower though the significance of the effect of treatment was fairly similar for each outcome.

For example, for smoking intensity the relative success rate for the primary outcome now estimated as 2.10 (0.77-5.76) (exact p = 0.06). While the estimated effect of treatment was always greater for smokers of 20+ cigs/day than for smokers of 1-19 cigs/day, significant heterogeneity was only evident for two of the secondary outcomes (cessation at week 6 in USA and 24 in Serbia, p = 0.02; cessation at week 16 in USA and 36 in Serbia, p = 0.02), the p-value being  $\geq 0.1$  for the other four outcomes). For the primary outcome the RR was 1.15 (0.33-4.01) for smokers of 10-19 cigs/day, where 5 of 9 quitters were in the active group, and 6.52 (1.18-36.15) for smokers of 20+ cigs/day, where 9 of 10 quitters were in the active group, with the heterogeneity p = 0.104.

TEXT-TABLE 5      Meta-analyses of effect of treatment on primary outcome by baseline characteristics

<u>Characteristic</u>	<u>Level</u>	% success rates (N)		<u>RR (95% CI)<sup>a</sup></u>	<u>Heterogeneity p</u>
		<u>Snus</u>	<u>Placebo</u>		
Gender	Male	5.83 (6)	0.85 (1)	4.64 (0.78-27.5)	0.169
	Female	4.44 (8)	2.38 (4)	1.81 (0.53-6.15)	
	Total	4.95 (14)	1.75 (5)	2.45 (0.90-6.71)	
Age	20-45	3.42 (5)	1.44 (2)	2.35 (0.46-12.0)	0.684
	46-64	6.57 (9)	2.04 (3)	3.21 (0.89-11.6)	
	Total	4.95 (14)	1.75 (5)	2.85 (1.04-7.82)	
Amount smoked	10-19	8.33 (5)	7.14 (4)	1.15 (0.33-4.01)	0.104
	20+	4.04 (9)	0.43 (1)	6.52 (1.18-36.2)	
	Total	4.95 (14)	1.75 (5)	2.10 (0.77-5.76)	
Age started to smoke	<18	4.00 (5)	1.53 (2)	2.60 (0.51-13.2)	0.691
	18+	5.70 (9)	1.94 (3)	2.89 (0.79-10.6)	
	Total	4.95 (14)	1.75 (5)	2.78 (1.01-7.65)	
Nicotine dependence score	0-6	4.09 (7)	2.99 (5)	1.37 (0.44-4.26)	0.114
	7+	6.25 (7)	0.00 (0)	8.46 (1.07-66.6)	
	Total	4.95 (14)	1.75 (5)	2.09 (0.77-5.65)	
Previous quit attempt	Yes	3.55 (6)	2.41 (4)	1.49 (0.43-5.18)	0.182
	No	7.02 (8)	0.83 (1)	6.29 (1.14-34.9)	
	Total	4.95 (14)	1.75 (5)	2.46 (0.90-6.72)	
Previous use of NRT	Yes	2.68 (2)	3.39 (2)	0.83 (0.12-5.68)	0.156
	No	5.63 (12)	1.32 (3)	3.58 (1.10-11.7)	
	Total	4.95 (14)	1.75 (5)	2.40 (0.88-6.57)	

a: All RRs are adjusted for study, total RRs are additionally adjusted for the given baseline characteristic.

**Table 6** presents results of analyses similar to those in **Table 3**, but restricted to compliant subjects, defined as those who used the product on average at least one day a week in each of weeks 1 to 5 (USA) or weeks 1 to 24 (Serbia). Compared to the intention-to-treat population, which included 250 subjects in the USA (125 active, 125 placebo) and 319 in Serbia (158 active, 161 placebo), these analyses were based on 200 subjects in the USA (99 active, 101 placebo) and 255 in Serbia (122 active, 133 placebo), with no significant evidence in either study that non-compliance rates varied by treatment.

These results are summarized in Text-Table 6, and it can be seen that the combined relative success rate estimates are quite similar to those in [Text-Table 4](#), with a significant ( $p<0.05$ ) advantage to the active treatment again seen for secondary outcomes 1-5. For the primary outcome, the estimate, now based on 16 successful outcomes rather than 17, is 3.09 (1.00-9.55, exact  $p = 0.054$ ).

TEXT-TABLE 6      Meta-analyses of effects of treatment (compliant subjects)

Outcome		USA	Serbia	Total (adjusted for study)
<b>PRIMARY OUTCOME</b>				
Cessation week 6-28 (USA) weeks 25-48 (Serbia)	n <sup>a</sup> RR	5/1 5.10 (0.61-42.88)	7/3 2.54 (0.67-9.62)	12/4 3.09 (1.00-9.55)
<b>SECONDARY OUTCOMES</b>				
1. Smoke-free week 6 (USA) week 24 (Serbia)	n <sup>a</sup> RR	22/10 2.24 (1.12-4.49)	6/3 2.18 (0.56-8.53)	28/13 2.23 (1.20-4.14)
2. Smoke-free week 16 (USA) week 36 (Serbia)	n <sup>a</sup> RR	20/9 2.27 (1.09-4.73)	13/6 2.36 (0.93-6.02)	35/15 2.30 (1.29-4.11)
3. Smoke-free week 28 (USA) week 48 (Serbia)	n <sup>a</sup> RR	16/8 2.04 (0.91-4.55)	23/14 1.79 (0.97-3.32)	39/22 1.88 (1.15-3.07)
4. Cessation weeks 25-28 (USA) weeks 45-48 (Serbia)	n <sup>a</sup> RR	13/6 2.21 (0.87-5.58)	20/12 1.82 (0.93-3.56)	33/18 1.94 (1.13-3.35)
5. Cessation weeks 17-28 (USA) weeks 37-48 (Serbia)	n <sup>a</sup> RR	12/5 2.45 (0.90-6.69)	13/6 2.36 (0.93-6.02)	25/11 2.40 (1.21-4.76)
Number of subjects	n <sup>b</sup>	99/101	122/133	221/234

<sup>a</sup> The first number shown is the number of successes in the active group, and the second is the number in the placebo group

<sup>b</sup> The first number shown is the number of subjects in the active group, and the second is the number in the placebo group

## DISCUSSION

While these two studies are to some extent different, partly because of the ready availability of smokeless tobacco products in the USA, but not in Serbia, the studies seem similar enough to allow valid meta-analysis. Given that meta-analyses are frequently conducted for observational epidemiological studies, where there may be variation in study designs (e.g. case-control or prospective cohort), types of exposure, and extent of adjustment for potential

confounding variables, there can be little objection to meta-analysis of relatively similar randomized controlled studies with the same active and placebo treatments.

In the main analysis, based on the primary outcome (biochemically validated smoking cessation at weeks 6 to 28 in the US study and at weeks 25 to 48 in the Serbian study) for the ITT population, there was an increased success rate in the group allocated to receive low nitrosamine snus. However this was based on only 14 successes (4.9% success rate) in the snus group, as against 5 (1.7% success rate) in the placebo group, and the relative success rate of 2.43 was not quite significant (exact p=0.06), with the 95% confidence interval 1.03-7.75. However, this outcome represents quite a stringent criterion, with the subjects having not to smoke at all over a period of over 20 weeks. Success rates were substantially higher, and the advantage to snus generally statistically significant for criteria based on success at specific weeks, or based on shorter periods. Notably this was true for criteria involving the end of the follow-up period, including secondary outcome 3 (smoke-free at week 28 in the USA and at week 48 in Serbia, with an RR of 1.73, 95% CI 1.07-2.78, based on combined study rates of 14.5% for snus and 8.4% for placebo) and secondary outcome 4 (cessation at weeks 25-28 in the USA and at weeks 45-48 in Serbia, with an RR of 1.86, 95% CI 1.09-3.18, based on combined study rates of 12.4% for snus and 6.6% for placebo). This strongly suggests that there is a real advantage to snus in encouraging quitting. It should be pointed out, however, that there is no information on whether those subjects who were smoke-free at the end of the study period were still smoke-free 6 months or a year later, and whether those who were continued to use snus or were tobacco-free.

## SUMMARY

Meta-analyses have been conducted based on two randomized placebo-controlled, double blind clinical trials, one conducted in the USA, and one in Serbia, of the effect of *ad lib* provision of low nitrosamine snus on quitting smoking. Both studies were of cigarette smokers of a similar age range and similar minimum daily cigarette consumption who did not use smokeless tobacco. The US study involved a 4 week post-randomization period during which the subjects were instructed to use the study products when they felt an urge to smoke, initially without any requirement for complete abstention, a 12 week intervention phase

during which subjects were encouraged to quit smoking completely and to use their allocated study product if they felt an urge to smoke, and a follow-up phase of 12 weeks. The Serbian study involved a 24 week post-randomization period during which the subjects were instructed to use the study products to cut down or preferably quit when they felt an urge to smoke, and a 24 week smoking cessation period, during which the subjects were instructed to quit smoking completely by use of the study products. In the Serbian study, subjects who failed to achieve a 50% smoking reduction in weeks 20-24 were withdrawn from the study at week 24.

The primary outcome was continuous smoking cessation (at each of weeks 6 to 28 US and 25 to 48 Serbia, confirmed by exhaled air CO values (<8 ppm at weeks 6, 10, 16 and 28 US and <10 ppm at weeks 30, 42 and 48 Serbia). Five secondary outcomes were defined based on continuous smoking cessation (CO confirmed) for shorter periods or based on being smoke-free (again CO confirmed) at specific weeks.

There were 250 subjects (125 active, 125 placebo) in the US study, and 319 (158 active, 161 placebo) in the Serbian study. The two studies had a similar frequency of males, and the subjects were of similar age and age of starting to smoke. Subjects in Serbia had a higher mean average daily cigarette consumption at baseline, 26.7, than subjects in the USA, 20.4, and a higher Fagerström nicotine dependence score. They were also less likely to have made a previous quit attempt, and very much less likely to have used NRT. There was no evidence in either study of failures of randomization, with the distribution of sex, age, cigarette consumption, age of starting to smoke, nicotine dependence score, previous quit attempts and previous use of NRT similar in the active and placebo groups.

None of the outcomes were significantly ( $p<0.05$ ) related to sex, age, age of starting to smoke, nicotine dependence score, previous quit attempts or previous use of NRT. However, in the studies combined, there was a significant ( $p<0.01$ ) tendency for outcome success rates to be greater in lighter smokers.

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Only 7 subjects in the USA and 12 in Serbia were successes as defined by the primary outcome. Although the relative success rate exceeded 2 in both the USA (2.50, 95% CI 0.49-12.65) and Serbia (3.06, 0.84-11.08), the meta-analysis estimate (2.83, 1.03-7.75) did not reach statistical significance (exact p = 0.06). Adjustment for previous cigarette consumption reduced the estimate to 2.10 (0.77-5.76), but the exact p value remained at 0.06. Although estimated success rates were higher in smokers of 20+ cigarettes per day (RR 6.52, 95% CI 1.18-36.15) than in smokers of 10-19 cigarettes per day (RR 1.15, 0.33-4.01), this heterogeneity was not significant (p = 0.10). Nor did success rates vary by the other baseline characteristics studied.

For the combined data, success rates for the five secondary outcomes were typically about twice as high in the active group as in the placebo group. For all five outcomes, this excess was statistically significant ( $p<0.05$ ). The significant excess for smoking cessation (CO confirmed) in the last 4 weeks of the study period, with success rates of 12.4% for snus vs. 6.6% for placebo (RR 1.86, 95% CI 1.09-3.18), suggests that there is a real advantage to snus in encouraging quitting.

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Table 1: Distribution of Main Outcomes by Confounding variables by Study  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

		Sex		
		1	2	Total
		Male	Female	
<b>Primary: Smoking cessation</b> <b>weeks 6-28(USA) 25-48(Serbia)</b>				
<b>Yes</b>				
<b>Serbia</b>	n	4	8	12
	N	123	196	319
	%	3.25	4.08	3.76
	Ex P		0.9568	
	RR		1.26	
<b>USA</b>	n	3	4	7
	N	98	152	250
	%	3.06	2.63	2.80
	Ex P		1.0000	
	RR		0.86	
<b>Total</b>	n	7	12	19
	N	221	348	569
	%	3.17	3.45	3.34
	Ex P		1.0000	
	RR		1.08	
	RR P		0.6945	
<b>Smoke-free week 6(USA)</b> <b>24(Serbia)</b>				
<b>Yes</b>				
<b>Serbia</b>	n	5	7	12
	N	123	196	319
	%	4.07	3.57	3.76
	Ex P		1.0000	
	RR		0.88	
<b>USA</b>	n	13	21	34
	N	98	152	250
	%	13.27	13.82	13.60
	Ex P		1.0000	
	RR		1.04	
<b>Total</b>	n	18	28	46
	N	221	348	569
	%	8.14	8.05	8.08
	Ex P		1.0000	
	RR		1.00	
	RR P		0.7970	

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		Sex		
		1 Male	2 Female	Total
<b>Smoke-free week 16(USA)</b>				
<b>36(Serbia)</b>				
Yes				
<b>Serbia</b>	n	7	14	21
	N	123	196	319
	%	5.69	7.14	6.58
	Ex P		0.7938	
	RR		1.26	
<b>USA</b>	n	12	20	32
	N	98	152	250
	%	12.24	13.16	12.80
	Ex P		0.9948	
	RR		1.07	
<b>Total</b>	n	19	34	53
	N	221	348	569
	%	8.60	9.77	9.31
	Ex P		0.7407	
	RR		1.14	
<b>Smoke-free week 28(USA)</b>				
	<b>48(Serbia)</b>			
	Yes			
<b>Serbia</b>	n	11	29	40
	N	123	196	319
	%	8.94	14.80	12.54
	Ex P		0.1695	
	RR		1.65	
<b>USA</b>	n	12	13	25
	N	98	152	250
	%	12.24	8.55	10.00
	Ex P		0.4599	
	RR		0.70	
<b>Total</b>	n	23	42	65
	N	221	348	569
	%	10.41	12.07	11.42
	Ex P		0.6459	
	RR		1.13	
RR P				
0.0881 (*)				

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Table 1: Distribution of Main Outcomes by Confounding variables by Study  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

		Sex		
		1 Male	2 Female	Total
<b>Smoking cessation weeks 25-</b>				
<b>28(USA) 45-48(Serbia)</b>				
<b>Yes</b>				
<b>Serbia</b>	n	9	25	34
	N	123	196	319
	%	7.32	12.76	10.66
	Ex P		0.1746	
	RR		1.74	
<b>USA</b>	n	9	11	20
	N	98	152	250
	%	9.18	7.24	8.00
	Ex P		0.7434	
	RR		0.79	
<b>Total</b>	n	18	36	54
	N	221	348	569
	%	8.14	10.34	9.49
	Ex P		0.4750	
	RR		1.24	
	RR P		0.1625	
<b>Smoking cessation weeks 17-</b>				
<b>28(USA) 37-48(Serbia)</b>				
<b>Yes</b>				
<b>Serbia</b>	n	7	14	21
	N	123	196	319
	%	5.69	7.14	6.58
	Ex P		0.7938	
	RR		1.26	
<b>USA</b>	n	8	10	18
	N	98	152	250
	%	8.16	6.58	7.20
	Ex P		0.8129	
	RR		0.81	
<b>Total</b>	n	15	24	39
	N	221	348	569
	%	6.79	6.90	6.85
	Ex P		1.0000	
	RR		1.01	
	RR P		0.4887	

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 Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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 A meta-analysis of results from two randomized clinical trials

		Age (grouped)				Total	Trend		
		1 20-36	2 37-45	3 46-52	4 53-64				
<b>Primary: Smoking cessation</b>									
weeks 6-28(USA) 24-48(Serbia)									
<b>Yes</b>									
<b>Serbia</b>	n	1	3	5	3	12			
	N	82	84	84	69	319			
	%	1.22	3.57	5.95	4.35	3.76			
	Ex P		0.6387	0.2215	0.4960		0.2575		
	RR		2.93	4.88	3.57				
<b>USA</b>	n	2	1	2	2	7			
	N	65	54	62	69	250			
	%	3.08	1.85	3.23	2.90	2.80			
	Ex P		1.0000	1.0000	1.0000		1.0000		
	RR		0.60	1.05	0.94				
<b>Total</b>	n	3	4	7	5	19			
	N	147	138	146	138	569			
	%	2.04	2.90	4.79	3.62	3.34			
	Ex P		0.9277	0.3324	0.6614		0.3536		
	RR		1.39	2.10	1.66				
	RR P		0.3422	0.2936	0.3777				
<b>Smoke-free week 6(USA)</b>									
24(Serbia)									
<b>Yes</b>									
<b>Serbia</b>	n	2	2	5	3	12			
	N	82	84	84	69	319			
	%	2.44	2.38	5.95	4.35	3.76			
	Ex P		1.0000	0.4631	0.8372		0.3875		
	RR		0.98	2.44	1.78				
<b>USA</b>	n	12	9	6	7	34			
	N	65	54	62	69	250			
	%	18.46	16.67	9.68	10.14	13.60			
	Ex P		0.9926	0.2437	0.2577		0.1145		
	RR		0.90	0.52	0.55				
<b>Total</b>	n	14	11	11	10	46			
	N	147	138	146	138	569			
	%	9.52	7.97	7.53	7.25	8.08			
	Ex P		0.9842	0.7259	0.4959		0.3998		
	RR		0.91	0.76	0.69				
	RR P		0.9415	0.1039	0.2400				

**CONFIDENTIAL**

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		Age (grouped)				Total	Trend			
		1 20-36	2 37-45	3 46-52	4 53-64					
<b>Smoke-free week 16(USA)</b>										
<b>36(Serbia)</b>										
<b>Yes</b>										
<b>Serbia</b>	n	6	4	6	5	21				
	N	82	84	84	69	319				
	%	7.32	4.76	7.14	7.25	6.58				
	Ex P		0.7160	1.0000	1.0000		0.9519			
	RR		0.65	0.98	0.99					
<b>USA</b>	n	12	6	7	7	32				
	N	65	54	62	69	250				
	%	18.46	11.11	11.29	10.14	12.80				
	Ex P		0.3928	0.3775	0.2577		0.2018			
	RR		0.60	0.61	0.55					
<b>Total</b>	n	18	10	13	12	53				
	N	147	138	146	138	569				
	%	12.24	7.25	8.90	8.70	9.31				
	Ex P		0.2712	0.4806	0.3699		0.3690			
	RR		0.62	0.73	0.68					
	RR P		0.9202	0.5100	0.4212					
<b>Smoke-free week 28(USA)</b>										
<b>48(Serbia)</b>										
<b>Yes</b>										
<b>Serbia</b>	n	12	6	13	9	40				
	N	82	84	84	69	319				
	%	14.63	7.14	15.48	13.04	12.54				
	Ex P		0.1920	1.0000	0.9679		0.8832			
	RR		0.49	1.06	0.89					
<b>USA</b>	n	8	4	4	9	25				
	N	65	54	62	69	250				
	%	12.31	7.41	6.45	13.04	10.00				
	Ex P		0.5686	0.4114	1.0000		1.0000			
	RR		0.60	0.52	1.06					
<b>Total</b>	n	20	10	17	18	65				
	N	147	138	146	138	569				
	%	13.61	7.25	11.64	13.04	11.42				
	Ex P		0.1159	0.7226	1.0000		0.8647			
	RR		0.53	0.87	0.96					
	RR P		0.7808	0.3109	0.7771					

**CONFIDENTIAL**

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		Age (grouped)				Total	Trend			
		1 20-36	2 37-45	3 46-52	4 53-64					
<b>Smoking cessation weeks 25-</b>										
<b>28(USA) 45-48(Serbia)</b>										
<b>Yes</b>										
<b>Serbia</b>	n	11	6	10	7	34				
	N	82	84	84	69	319				
	%	13.41	7.14	11.90	10.14	10.66				
	Ex P		0.2816	0.9525	0.7193		0.8153			
	RR		0.53	0.89	0.76					
<b>USA</b>	n	7	4	4	5	20				
	N	65	54	62	69	250				
	%	10.77	7.41	6.45	7.25	8.00				
	Ex P		0.7620	0.5860	0.6811		0.5056			
	RR		0.69	0.60	0.67					
<b>Total</b>	n	18	10	14	12	54				
	N	147	138	146	138	569				
	%	12.24	7.25	9.59	8.70	9.49				
	Ex P		0.2172	0.5755	0.4625		0.5037			
	RR		0.59	0.78	0.72					
	RR P		0.7394	0.5887	0.8713					
<b>Smoking cessation weeks 17-</b>										
<b>28(USA) 37-48(Serbia)</b>										
<b>Yes</b>										
<b>Serbia</b>	n	7	4	6	4	21				
	N	82	84	84	69	319				
	%	8.54	4.76	7.14	5.80	6.58				
	Ex P		0.5073	0.9633	0.7478		0.7260			
	RR		0.56	0.84	0.68					
<b>USA</b>	n	7	4	3	4	18				
	N	65	54	62	69	250				
	%	10.77	7.41	4.84	5.80	7.20				
	Ex P		0.7620	0.3638	0.4644		0.2694			
	RR		0.69	0.45	0.54					
<b>Total</b>	n	14	8	9	8	39				
	N	147	138	146	138	569				
	%	9.52	5.80	6.16	5.80	6.85				
	Ex P		0.3609	0.3958	0.3309		0.2717			
	RR		0.62	0.66	0.60					
	RR P		0.8060	0.4668	0.7856					

**CONFIDENTIAL**

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		Age Start Smoking (grouped)					Total	Trend
		1 8-15	2 16-17	3 18-19	4 20-21	5 22-53		
<b>Primary: Smoking cessation weeks 6-28(USA) 24-48(Serbia)</b>								
<b>Yes</b>								
<b>Serbia</b>	n	2	1	5	1	3	12	
	N	54	67	89	59	50	319	
	%	3.70	1.49	5.62	1.69	6.00	3.76	
	Ex P		0.8381	0.9346	0.9331	0.9265		0.6368
	RR		0.40	1.52	0.46	1.62		
<b>USA</b>	n	2	2	0	2	1	7	
	N	77	58	44	33	38	250	
	%	2.60	3.45	0.00	6.06	2.63	2.80	
	Ex P		1.0000	0.8061	0.6949	1.0000		0.8992
	RR		1.33	0.35	2.33	1.01		
<b>Total</b>	n	4	3	5	3	4	19	
	N	131	125	133	92	88	569	
	%	3.05	2.40	3.76	3.26	4.55	3.34	
	Ex P		1.0000	1.0000	1.0000	0.9250		0.6041
	RR		0.83	1.09	1.23	1.37		
	RR P		0.4450	0.3969	0.2951	0.7546		
<b>Smoke-free week 6(USA) 24(Serbia)</b>								
<b>Yes</b>								
<b>Serbia</b>	n	2	1	5	1	3	12	
	N	54	67	89	59	50	319	
	%	3.70	1.49	5.62	1.69	6.00	3.76	
	Ex P		0.8381	0.9346	0.9331	0.9265		0.6368
	RR		0.40	1.52	0.46	1.62		
<b>USA</b>	n	11	9	4	6	4	34	
	N	77	58	44	33	38	250	
	%	14.29	15.52	9.09	18.18	10.53	13.60	
	Ex P		1.0000	0.5956	0.7987	0.8076		0.7553
	RR		1.09	0.64	1.27	0.74		
<b>Total</b>	n	13	10	9	7	7	46	
	N	131	125	133	92	88	569	
	%	9.92	8.00	6.77	7.61	7.95	8.08	
	Ex P		1.0000	0.8888	1.0000	1.0000		1.0000
	RR		0.98	0.84	1.12	0.92		
	RR P		0.4385	0.3791	0.4299	0.4518		

**CONFIDENTIAL**

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		Age Start Smoking (grouped)					Total	Trend
		1 8-15	2 16-17	3 18-19	4 20-21	5 22-53		
<b>Smoke-free week 16(USA)</b>								
<b>36(Serbia)</b>								
<b>Yes</b>								
<b>Serbia</b>	n	2	4	11	1	3	21	
	N	54	67	89	59	50	319	
	%	3.70	5.97	12.36	1.69	6.00	6.58	
	Ex P		0.8941	0.1389	0.9331	0.9265		1.0000
	RR		1.61	3.34	0.46	1.62		
<b>USA</b>	n	9	10	3	6	4	32	
	N	77	58	44	33	38	250	
	%	11.69	17.24	6.82	18.18	10.53	12.80	
	Ex P		0.5016	0.5990	0.5328	1.0000		0.9748
	RR		1.48	0.58	1.56	0.90		
<b>Total</b>	n	11	14	14	7	7	53	
	N	131	125	133	92	88	569	
	%	8.40	11.20	10.53	7.61	7.95	9.31	
	Ex P		0.3869	0.6502	0.8014	1.0000		0.9824
	RR		1.50	1.22	1.31	1.07		
	RR P		0.9254	0.0766 (*)	0.3479	0.5785		
<b>Smoke-free week 28(USA)</b>								
<b>48(Serbia)</b>								
<b>Yes</b>								
<b>Serbia</b>	n	4	9	14	8	5	40	
	N	54	67	89	59	50	319	
	%	7.41	13.43	15.73	13.56	10.00	12.54	
	Ex P		0.4456	0.2287	0.4529	0.9017		0.7452
	RR		1.81	2.12	1.83	1.35		
<b>USA</b>	n	7	9	2	4	3	25	
	N	77	58	44	33	38	250	
	%	9.09	15.52	4.55	12.12	7.89	10.00	
	Ex P		0.3810	0.5952	0.8607	1.0000		0.7552
	RR		1.71	0.50	1.33	0.87		
<b>Total</b>	n	11	18	16	12	8	65	
	N	131	125	133	92	88	569	
	%	8.40	14.40	12.03	13.04	9.09	11.42	
	Ex P		0.1732	0.6684	0.3749	1.0000		1.0000
	RR		1.75	1.33	1.57	1.09		
	RR P		0.9350	0.1271	0.7026	0.6319		

**CONFIDENTIAL**

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		Age Start Smoking (grouped)					Total	Trend
		1 8-15	2 16-17	3 18-19	4 20-21	5 22-53		
<b>Smoking cessation weeks 25-28(USA) 45-48(Serbia)</b>								
Yes								
<b>Serbia</b>	n	4	7	13	6	4	34	
	N	54	67	89	59	50	319	
	%	7.41	10.45	14.61	10.17	8.00	10.66	
	Ex P		0.8031	0.3060	0.8577	1.0000		0.9762
	RR		1.41	1.97	1.37	1.08		
<b>USA</b>	n	6	6	2	4	2	20	
	N	77	58	44	33	38	250	
	%	7.79	10.34	4.55	12.12	5.26	8.00	
	Ex P		0.8253	0.7805	0.6928	0.9437		0.8489
	RR		1.33	0.58	1.56	0.68		
<b>Total</b>	n	10	13	15	10	6	54	
	N	131	125	133	92	88	569	
	%	7.63	10.40	11.28	10.87	6.82	9.49	
	Ex P		0.5816	0.6622	0.5289	1.0000		0.9568
	RR		1.36	1.34	1.46	0.89		
	RR P		0.9407	0.2061	0.8857	0.6529		
<b>Smoking cessation weeks 17-28(USA) 37-48(Serbia)</b>								
Yes								
<b>Serbia</b>	n	2	4	10	2	3	21	
	N	54	67	89	59	50	319	
	%	3.70	5.97	11.24	3.39	6.00	6.58	
	Ex P		0.8941	0.1997	1.0000	0.9265		0.9226
	RR		1.61	3.03	0.92	1.62		
<b>USA</b>	n	6	5	1	4	2	18	
	N	77	58	44	33	38	250	
	%	7.79	8.62	2.27	12.12	5.26	7.20	
	Ex P		1.0000	0.4066	0.6928	0.9437		0.8654
	RR		1.11	0.29	1.56	0.68		
<b>Total</b>	n	8	9	11	6	5	39	
	N	131	125	133	92	88	569	
	%	6.11	7.20	8.27	6.52	5.68	6.85	
	Ex P		0.8172	0.8136	0.7943	1.0000		1.0000
	RR		1.25	1.38	1.34	0.99		
	RR P		0.7138	0.0726 (*)	0.6466	0.4632		

**CONFIDENTIAL**

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		Average cigarettes per day (previous year) (grouped)					Total	Trend		
		10-19	20	21-30	31-60					
<b>Primary: Smoking cessation weeks 6-28(USA) 25-48(Serbia)</b>										
Yes										
<b>Serbia</b>	n	5	4	2	1	12				
	N	32	114	112	61	319				
	%	15.63	3.51	1.79	1.64	3.76				
	Ex P		0.0491 -	0.0124 -	0.0346 -		0.0075 --			
	RR		0.22	0.11	0.10					
<b>USA</b>	n	4	3	0	0	7				
	N	84	108	45	13	250				
	%	4.76	2.78	0.00	0.00	2.80				
	Ex P		0.7266	0.3505	1.0000		0.1428			
	RR		0.58	0.21	0.67					
<b>Total</b>	n	9	7	2	1	19				
	N	116	222	157	74	569				
	%	7.76	3.15	1.27	1.35	3.34				
	Ex P		0.0552 (-)	0.0025 --	0.0201 -		0.0013 --			
	RR		0.34	0.13	0.20					
	RR P		0.3330	0.7285	0.3050					
<b>Smoke-free week 6(USA) 24(Serbia)</b>										
Yes										
<b>Serbia</b>	n	5	3	3	1	12				
	N	32	114	112	61	319				
	%	15.63	2.63	2.68	1.64	3.76				
	Ex P		0.0259 -	0.0276 -	0.0346 -		0.0197 -			
	RR		0.17	0.17	0.10					
<b>USA</b>	n	17	14	2	1	34				
	N	84	108	45	13	250				
	%	20.24	12.96	4.44	7.69	13.60				
	Ex P		0.2460	0.0232 -	0.5088		0.0160 -			
	RR		0.64	0.22	0.38					
<b>Total</b>	n	22	17	5	2	46				
	N	116	222	157	74	569				
	%	18.97	7.66	3.18	2.70	8.08				
	Ex P		0.0274 -	0.0007 ---	0.0193 -		0.0006 ---			
	RR		0.50	0.19	0.21					
	RR P		0.0852 (*)	0.8061	0.3769					

**CONFIDENTIAL**

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		Average cigarettes per day (previous year) (grouped)					Total	Trend		
		1 10-19	2 20	3 21-30	4 31-60					
<b>Smoke-free week 16(USA)</b>										
<b>36(Serbia)</b>										
Yes										
<b>Serbia</b>	n	7	6	5	3	21				
	N	32	114	112	61	319				
	%	21.88	5.26	4.46	4.92	6.58				
	Ex P		0.0169 -	0.0101 -	0.0352 -			0.0274 -		
	RR		0.24	0.20	0.22					
<b>USA</b>	n	18	12	1	1	32				
	N	84	108	45	13	250				
	%	21.43	11.11	2.22	7.69	12.80				
	Ex P		0.0804 (-)	0.0036 --	0.4487			0.0026 --		
	RR		0.52	0.10	0.36					
<b>Total</b>	n	25	18	6	4	53				
	N	116	222	157	74	569				
	%	21.55	8.11	3.82	5.41	9.31				
	Ex P		0.0035 --	0.0000 ---	0.0150 -			0.0002 ---		
	RR		0.41	0.17	0.26					
<b>Smoke-free week 28(USA)</b>										
	<b>48(Serbia)</b>									
Yes										
<b>Serbia</b>	n	12	13	11	4	40				
	N	32	114	112	61	319				
	%	37.50	11.40	9.82	6.56	12.54				
	Ex P		0.0026 --	0.0011 --	0.0007 ---			0.0008 ---		
	RR		0.30	0.26	0.17					
<b>USA</b>	n	13	8	2	2	25				
	N	84	108	45	13	250				
	%	15.48	7.41	4.44	15.38	10.00				
	Ex P		0.1235	0.1039	1.0000			0.1932		
	RR		0.48	0.29	0.99					
<b>Total</b>	n	25	21	13	6	65				
	N	116	222	157	74	569				
	%	21.55	9.46	8.28	8.11	11.42				
	Ex P		0.0008 ---	0.0001 ---	0.0037 --			0.0003 ---		
	RR		0.36	0.27	0.33					
	RR P		0.4084	0.9108	0.0482 *					

**CONFIDENTIAL**

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		Average cigarettes per day (previous year) (grouped)				Total	Trend		
		10-19	20	21-30	31-60				
<b>Smoking cessation weeks 25-</b>									
<b>28(USA) 45-48(Serbia)</b>									
<b>Yes</b>									
<b>Serbia</b>	n	9	12	10	3	34			
	N	32	114	112	61	319			
	%	28.13	10.53	8.93	4.92	10.66			
	Ex P		0.0339 -	0.0166 -	0.0055 --		0.0046 --		
	RR		0.37	0.32	0.17				
<b>USA</b>	n	10	7	2	1	20			
	N	84	108	45	13	250			
	%	11.90	6.48	4.44	7.69	8.00			
	Ex P		0.2912	0.2815	1.0000		0.2176		
	RR		0.54	0.37	0.65				
<b>Total</b>	n	19	19	12	4	54			
	N	116	222	157	74	569			
	%	16.38	8.56	7.64	5.41	9.49			
	Ex P		0.0160 -	0.0054 --	0.0081 --		0.0018 --		
	RR		0.44	0.33	0.25				
	RR P		0.5411	0.8502	0.2707				
<b>Smoking cessation weeks 17-</b>									
<b>28(USA) 37-48(Serbia)</b>									
<b>Yes</b>									
<b>Serbia</b>	n	7	7	4	3	21			
	N	32	114	112	61	319			
	%	21.88	6.14	3.57	4.92	6.58			
	Ex P		0.0284 -	0.0050 --	0.0352 -		0.0138 -		
	RR		0.28	0.16	0.22				
<b>USA</b>	n	10	6	1	1	18			
	N	84	108	45	13	250			
	%	11.90	5.56	2.22	7.69	7.20			
	Ex P		0.1891	0.1074	1.0000		0.1005		
	RR		0.47	0.19	0.65				
<b>Total</b>	n	17	13	5	4	39			
	N	116	222	157	74	569			
	%	14.66	5.86	3.18	5.41	6.85			
	Ex P		0.0089 --	0.0005 ---	0.0427 -		0.0022 --		
	RR		0.36	0.17	0.31				
	RR P		0.4683	0.9105	0.3789				

**CONFIDENTIAL**

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		Fagerström Dependency Test (grouped)					Total	Trend
		1 0-4	2 5	3 6	4 7	5 8-10		
<b>Primary: Smoking cessation</b>								
weeks 6-28(USA) 25-48(Serbia)								
<b>Yes</b>								
<b>Serbia</b>	n	4	3	1	1	3	12	
	N	68	41	60	58	92	319	
	%	5.88	7.32	1.67	1.72	3.26	3.76	
	Ex P		1.0000	0.4482	0.4722	0.6732		0.2513
	RR		1.24	0.28	0.29	0.55		
<b>USA</b>	n	2	0	2	2	1	7	
	N	72	49	48	35	46	250	
	%	2.78	0.00	4.17	5.71	2.17	2.80	
	Ex P		0.7041	1.0000	0.7923	1.0000		0.7201
	RR		0.29	1.50	2.06	0.78		
<b>Total</b>	n	6	3	3	3	4	19	
	N	140	90	108	93	138	569	
	%	4.29	3.33	2.78	3.23	2.90	3.34	
	Ex P		1.0000	0.7730	0.9565	0.6494		0.5248
	RR		0.95	0.72	0.87	0.61		
	RR P		0.3956	0.2594	0.1865	0.8084		
<b>Smoke-free week 6(USA)</b>								
24(Serbia)								
<b>Yes</b>								
<b>Serbia</b>	n	3	3	1	2	3	12	
	N	68	41	60	58	92	319	
	%	4.41	7.32	1.67	3.45	3.26	3.76	
	Ex P		0.8102	0.7164	1.0000	1.0000		0.5661
	RR		1.66	0.38	0.78	0.74		
<b>USA</b>	n	10	5	9	6	4	34	
	N	72	49	48	35	46	250	
	%	13.89	10.20	18.75	17.14	8.70	13.60	
	Ex P		0.7574	0.6401	0.8597	0.5859		0.8535
	RR		0.73	1.35	1.23	0.63		
<b>Total</b>	n	13	8	10	8	7	46	
	N	140	90	108	93	138	569	
	%	9.29	8.89	9.26	8.60	5.07	8.08	
	Ex P		1.0000	0.9834	1.0000	0.5029		0.6022
	RR		0.94	1.16	1.12	0.66		
	RR P		0.3890	0.2949	0.6519	0.8652		

**CONFIDENTIAL**

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		Fagerström Dependency Test (grouped)					Total	Trend
		1 0-4	2 5	3 6	4 7	5 8-10		
<b>Smoke-free week 16(USA)</b>								
<b>36(Serbia)</b>								
Yes								
<b>Serbia</b>	n	6	3	3	3	6	21	
	N	68	41	60	58	92	319	
	%	8.82	7.32	5.00	5.17	6.52	6.58	
	Ex P		1.0000	0.6247	0.6629	0.7996		0.5714
	RR		0.83	0.57	0.59	0.74		
<b>USA</b>	n	14	5	5	6	2	32	
	N	72	49	48	35	46	250	
	%	19.44	10.20	10.42	17.14	4.35	12.80	
	Ex P		0.2626	0.2829	0.9980	0.0315 -		0.0679 (-)
	RR		0.52	0.54	0.88	0.22		
<b>Total</b>	n	20	8	8	9	8	53	
	N	140	90	108	93	138	569	
	%	14.29	8.89	7.41	9.68	5.80	9.31	
	Ex P		0.2841	0.1705	0.6259	0.0565 (-)		0.0734 (-)
	RR		0.61	0.55	0.78	0.48		
	RR P		0.5839	0.9467	0.6164	0.1930		
<b>Smoke-free week 28(USA)</b>								
<b>48(Serbia)</b>								
Yes								
<b>Serbia</b>	n	14	6	5	4	11	40	
	N	68	41	60	58	92	319	
	%	20.59	14.63	8.33	6.90	11.96	12.54	
	Ex P		0.6093	0.0864 (-)	0.0491 -	0.2064		0.0813 (-)
	RR		0.71	0.40	0.33	0.58		
<b>USA</b>	n	10	1	4	5	5	25	
	N	72	49	48	35	46	250	
	%	13.89	2.04	8.33	14.29	10.87	10.00	
	Ex P		0.0459 -	0.5307	1.0000	0.8568		0.9826
	RR		0.15	0.60	1.03	0.78		
<b>Total</b>	n	24	7	9	9	16	65	
	N	140	90	108	93	138	569	
	%	17.14	7.78	8.33	9.68	11.59	11.42	
	Ex P		0.0684 (-)	0.0556 (-)	0.1500	0.1958		0.1847
	RR		0.55	0.48	0.61	0.64		
	RR P		0.1610	0.5973	0.1293	0.6376		

**CONFIDENTIAL**

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		Fagerström Dependency Test (grouped)					Total	Trend
		1 0-4	2 5	3 6	4 7	5 8-10		
<b>Smoking cessation weeks 25-</b>								
<b>28(USA) 45-48(Serbia)</b>								
<b>Yes</b>								
<b>Serbia</b>	n	12	5	4	4	9	34	
	N	68	41	60	58	92	319	
	%	17.65	12.20	6.67	6.90	9.78	10.66	
	Ex P		0.6359	0.1044	0.1201	0.2236		0.1086
	RR		0.69	0.38	0.39	0.55		
<b>USA</b>	n	7	1	4	4	4	20	
	N	72	49	48	35	46	250	
	%	9.72	2.04	8.33	11.43	8.70	8.00	
	Ex P		0.1871	1.0000	1.0000	1.0000		0.7732
	RR		0.21	0.86	1.18	0.89		
<b>Total</b>	n	19	6	8	8	13	54	
	N	140	90	108	93	138	569	
	%	13.57	6.67	7.41	8.60	9.42	9.49	
	Ex P		0.1641	0.1589	0.3003	0.2739		0.2867
	RR		0.56	0.55	0.65	0.65		
	RR P		0.3056	0.3133	0.1725	0.5096		
<b>Smoking cessation weeks 17-</b>								
<b>28(USA) 37-48(Serbia)</b>								
<b>Yes</b>								
<b>Serbia</b>	n	7	4	2	3	5	21	
	N	68	41	60	58	92	319	
	%	10.29	9.76	3.33	5.17	5.43	6.58	
	Ex P		1.0000	0.2317	0.4701	0.3942		0.1924
	RR		0.95	0.32	0.50	0.53		
<b>USA</b>	n	6	1	3	4	4	18	
	N	72	49	48	35	46	250	
	%	8.33	2.04	6.25	11.43	8.70	7.20	
	Ex P		0.2892	0.9608	0.8458	1.0000		0.5867
	RR		0.24	0.75	1.37	1.04		
<b>Total</b>	n	13	5	5	7	9	39	
	N	140	90	108	93	138	569	
	%	9.29	5.56	4.63	7.53	6.52	6.85	
	Ex P		0.4631	0.2503	0.8679	0.5589		0.5774
	RR		0.69	0.52	0.87	0.72		
	RR P		0.2670	0.4183	0.2671	0.4149		

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		Previous quit attempt		
		1 Yes	2 No	Total
<b>Primary: Smoking cessation</b>				
<b>weeks 6-28(USA) 25-48(Serbia)</b>				
<b>Yes</b>				
<b>Serbia</b>	n	5	7	12
	N	116	203	319
	%	4.31	3.45	3.76
	Ex P		0.9130	
	RR		0.80	
<b>USA</b>	n	5	2	7
	N	219	31	250
	%	2.28	6.45	2.80
	Ex P		0.4210	
	RR		2.83	
<b>Total</b>	n	10	9	19
	N	335	234	569
	%	2.99	3.85	3.34
	Ex P		1.0000	
	RR		1.22	
	RR P		0.2053	
<b>Smoke-free week 6(USA)</b>				
<b>24(Serbia)</b>				
<b>Yes</b>				
<b>Serbia</b>	n	5	7	12
	N	116	203	319
	%	4.31	3.45	3.76
	Ex P		0.9130	
	RR		0.80	
<b>USA</b>	n	32	2	34
	N	219	31	250
	%	14.61	6.45	13.60
	Ex P		0.3382	
	RR		0.44	
<b>Total</b>	n	37	9	46
	N	335	234	569
	%	11.04	3.85	8.08
	Ex P		0.3305	
	RR		0.63	
	RR P		0.5126	

**CONFIDENTIAL**

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		Previous quit attempt				
		1	2	Total		
		Yes	No			
<b>Smoke-free week 16(USA)</b>						
<b>36(Serbia)</b>						
Yes						
<b>Serbia</b>	n	9	12	21		
	N	116	203	319		
	%	7.76	5.91	6.58		
	Ex P		0.6746			
	RR		0.76			
<b>USA</b>	n	29	3	32		
	N	219	31	250		
	%	13.24	9.68	12.80		
	Ex P		0.8296			
	RR		0.73			
<b>Total</b>	n	38	15	53		
	N	335	234	569		
	%	11.34	6.41	9.31		
	Ex P		0.5070			
	RR		0.75			
	RR P		0.9536			
<b>Smoke-free week 28(USA)</b>						
<b>48(Serbia)</b>						
Yes						
<b>Serbia</b>	n	19	21	40		
	N	116	203	319		
	%	16.38	10.34	12.54		
	Ex P		0.1672			
	RR		0.63			
<b>USA</b>	n	23	2	25		
	N	219	31	250		
	%	10.50	6.45	10.00		
	Ex P		0.7469			
	RR		0.61			
<b>Total</b>	n	42	23	65		
	N	335	234	569		
	%	12.54	9.83	11.42		
	Ex P		0.1191			
	RR		0.63			
	RR P		0.9713			

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Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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		Previous quit attempt		
		1	2	
		Yes	No	Total
<b>Smoking cessation weeks 25-</b>				
<b>28(USA) 45-48(Serbia)</b>				
<b>Yes</b>				
<b>Serbia</b>	n	15	19	34
	N	116	203	319
	%	12.93	9.36	10.66
	Ex P		0.4179	
	RR		0.72	
<b>USA</b>	n	18	2	20
	N	219	31	250
	%	8.22	6.45	8.00
	Ex P		1.0000	
	RR		0.78	
<b>Total</b>	n	33	21	54
	N	335	234	569
	%	9.85	8.97	9.49
	Ex P		0.3833	
	RR		0.73	
	RR P		0.9183	
<b>Smoking cessation weeks 17-</b>				
<b>28(USA) 37-48(Serbia)</b>				
<b>Yes</b>				
<b>Serbia</b>	n	9	12	21
	N	116	203	319
	%	7.76	5.91	6.58
	Ex P		0.6746	
	RR		0.76	
<b>USA</b>	n	16	2	18
	N	219	31	250
	%	7.31	6.45	7.20
	Ex P		1.0000	
	RR		0.88	
<b>Total</b>	n	25	14	39
	N	335	234	569
	%	7.46	5.98	6.85
	Ex P		0.6639	
	RR		0.79	
	RR P		0.8606	

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Table 1: Distribution of Main Outcomes by Confounding variables by Study  
 Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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		Previous exposure to NRT		
		1 Yes	2 No	Total
<b>Primary: Smoking cessation</b>				
weeks 6-28(USA) 25-48(Serbia)				
<b>Yes</b>				
<b>Serbia</b>	n	0	12	12
	N	3	316	319
	%	0.00	3.80	3.76
	Ex P		1.0000	
	RR		0.32	
<b>USA</b>	n	4	3	7
	N	126	124	250
	%	3.17	2.42	2.80
	Ex P		1.0000	
	RR		0.76	
<b>Total</b>	n	4	15	19
	N	129	440	569
	%	3.10	3.41	3.34
	Ex P		1.0000	
	RR		0.62	
	RR P		0.5686	
<b>Smoke-free week 6(USA)</b>				
24(Serbia)				
<b>Yes</b>				
<b>Serbia</b>	n	1	11	12
	N	3	316	319
	%	33.33	3.48	3.76
	Ex P		0.2180	
	RR		0.10	
<b>USA</b>	n	20	14	34
	N	126	124	250
	%	15.87	11.29	13.60
	Ex P		0.3833	
	RR		0.71	
<b>Total</b>	n	21	25	46
	N	129	440	569
	%	16.28	5.68	8.08
	Ex P		0.2333	
	RR		0.56	
	RR P		0.0385 *	

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Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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		Previous exposure to NRT		
		1 Yes	2 No	Total
<b>Smoke-free week 16(USA)</b>				
<b>36(Serbia)</b>				
Yes				
<b>Serbia</b>	n	0	21	21
	N	3	316	319
	%	0.00	6.65	6.58
	Ex P		1.0000	
	RR		0.54	
<b>USA</b>	n	15	17	32
	N	126	124	250
	%	11.90	13.71	12.80
	Ex P		0.8121	
	RR		1.15	
<b>Total</b>	n	15	38	53
	N	129	440	569
	%	11.63	8.64	9.31
	Ex P		0.7587	
	RR		1.10	
	RR P		0.5854	
<b>Smoke-free week 28(USA)</b>				
<b>48(Serbia)</b>				
Yes				
<b>Serbia</b>	n	0	40	40
	N	3	316	319
	%	0.00	12.66	12.54
	Ex P		1.0000	
	RR		1.02	
<b>USA</b>	n	14	11	25
	N	126	124	250
	%	11.11	8.87	10.00
	Ex P		0.7053	
	RR		0.80	
<b>Total</b>	n	14	51	65
	N	129	440	569
	%	10.85	11.59	11.42
	Ex P		0.8286	
	RR		0.81	
	RR P		0.8584	

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		Previous exposure to NRT		
		1 Yes	2 No	Total
<b>Smoking cessation weeks 25-</b>				
<b>28(USA) 45-48(Serbia)</b>				
<b>Yes</b>				
<b>Serbia</b>	n	0	34	34
	N	3	316	319
	%	0.00	10.76	10.66
	Ex P		1.0000	
	RR		0.87	
<b>USA</b>	n	11	9	20
	N	126	124	250
	%	8.73	7.26	8.00
	Ex P		0.8457	
	RR		0.83	
<b>Total</b>	n	11	43	54
	N	129	440	569
	%	8.53	9.77	9.49
	Ex P		0.9616	
	RR		0.84	
	RR P		0.9737	
<b>Smoking cessation weeks 17-</b>				
<b>28(USA) 37-48(Serbia)</b>				
<b>Yes</b>				
<b>Serbia</b>	n	0	21	21
	N	3	316	319
	%	0.00	6.65	6.58
	Ex P		1.0000	
	RR		0.54	
<b>USA</b>	n	10	8	18
	N	126	124	250
	%	7.94	6.45	7.20
	Ex P		0.8352	
	RR		0.81	
<b>Total</b>	n	10	29	39
	N	129	440	569
	%	7.75	6.59	6.85
	Ex P		0.9106	
	RR		0.78	
	RR P		0.7751	

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Table 2: Analysis of Confounding variables by Study  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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Sex		Group		
		1 Active	2 Placebo	Total
<b>Male</b>				
<b>Serbia</b>	E	60.92	62.08	
	N	158	161	319
	%	37.34	39.75	38.56
	ChiSq	0.19		
	Chi P	0.6589		
	Ex P	0.7437		
<b>USA</b>	E	49.00	49.00	
	N	125	125	250
	%	35.20	43.20	39.20
	ChiSq	1.67		
	Chi P	0.1960		
	Ex P	0.2436		
<b>Total</b>	E	109.92	111.08	
	N	283	286	569
	%	36.40	41.26	38.84
	ChiSq	1.41		
	Chi P	0.2346		
	Ex P			

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Table 2: Analysis of Confounding variables by Study  
 Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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	N	Group		Total
		1 Active	2 Placebo	
<b>Age (grouped)</b>				
<b>Serbia</b>				
<b>20-36</b>	158	161	319	
37-45	40	42	82	
46-52	44	40	84	
53-64	46	38	84	
	28	41	69	
<b>USA</b>				
<b>20-36</b>	125	125	250	
37-45	36	29	65	
46-52	26	28	54	
53-64	31	31	62	
	32	37	69	
<b>Age (Years)</b>				
<b>Serbia</b>	N	158	161	319
	Mean	43.30	43.98	43.64
	St.Err	0.79	0.81	0.56
	St.Dev	9.89	10.30	10.09
	Median	45.00	45.00	45.00
	Range	20.00:64.00	21.00:62.00	20.00:64.00
	Q25:75	36.00:51.00	36.00:53.00	36.00:52.00
	KWS	0.47		
	KW P	0.4929		
<b>USA</b>	N	125	125	250
	Mean	44.34	45.74	45.04
	St.Err	0.98	0.98	0.69
	St.Dev	10.94	10.93	10.93
	Median	46.00	47.00	46.00
	Range	25.00:64.00	25.00:64.00	25.00:64.00
	Q25:75	34.00:53.00	38.00:54.00	36.00:53.00
	KWS	0.99		
	KW P	0.3202		
<b>Total</b>	N	283	286	569
	Mean	43.76	44.75	44.25
	St.Err	0.62	0.63	0.44
	St.Dev	10.36	10.60	10.48
	KWD	-8.08	8.08	
	KWS	1.37		
	KW P	0.2410		

**CONFIDENTIAL**

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 Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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		Group		Total
		1 Active	2 Placebo	
<b>Age Start Smoking (grouped)</b>				
<b>Serbia</b>	N	158	161	319
<b>8-15</b>		22	32	54
<b>16-17</b>		35	32	67
<b>18-19</b>		46	43	89
<b>20-21</b>		34	25	59
<b>22-53</b>		21	29	50
<b>USA</b>	N	125	125	250
<b>8-15</b>		38	39	77
<b>16-17</b>		30	28	58
<b>18-19</b>		19	25	44
<b>20-21</b>		21	12	33
<b>22-53</b>		17	21	38
<b>Age started smoking (years)</b>				
<b>Serbia</b>	N	158	161	319
	Mean	19.20	18.83	19.01
	St.Err	0.42	0.31	0.26
	St.Dev	5.32	3.96	4.68
	Median	18.00	18.00	18.00
	Range	10:53	12:35	10:53
	Q25:75	17.00:20.00	16.00:20.00	17.00:20.00
	KWS	0.14		
	KW P	0.7127		
<b>USA</b>	N	125	125	250
	Mean	18.05	18.73	18.39
	St.Err	0.49	0.64	0.40
	St.Dev	5.51	7.13	6.37
	Median	17.00	17.00	17.00
	Range	8:51	8:49	8:51
	Q25:75	15.00:20.00	15.00:20.00	15.00:20.00
	KWS	0.01		
	KW P	0.9286		
<b>Total</b>	N	283	286	569
	Mean	18.69	18.79	18.74
	St.Err	0.32	0.33	0.23
	St.Dev	5.43	5.56	5.49
	KWD	2.30	-2.30	
	KWS	0.11		
	KW P	0.7378		

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Table 2: Analysis of Confounding variables by Study  
 Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
 on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
 A meta-analysis of results from two randomized clinical trials

		Group		Total	
		1 Active	2 Placebo		
<b>Average cigarettes per day (previous year)</b>					
(grouped)					
Serbia					
10-19	N	158	161	319	
20		17	15	32	
21-30		50	64	114	
31-60		58	54	112	
		33	28	61	
USA					
10-19	N	125	125	250	
20		43	41	84	
21-30		53	55	108	
31-60		22	23	45	
		7	6	13	
<b>Average Cigarettes per day (previous year)</b>					
Serbia					
N	158	161	319		
Mean	27.63	25.71	26.66		
St.Err	0.83	0.71	0.55		
St.Dev	10.49	8.96	9.78		
Median	25.00	25.00	25.00		
Range	10:60	10:60	10:60		
Q25:75	20.00:30.00	20.00:30.00	20.00:30.00		
KWS	2.08				
KW P	0.1488				
USA					
N	125	125	250		
Mean	20.17	20.63	20.40		
St.Err	0.70	0.72	0.50		
St.Dev	7.82	8.05	7.92		
Median	20.00	20.00	20.00		
Range	10:60	10:60	10:60		
Q25:75	15.00:20.00	15.00:20.00	15.00:20.00		
KWS	0.11				
KW P	0.7391				
<b>Total</b>					
N	283	286	569		
Mean	24.33	23.49	23.91		
St.Err	0.60	0.53	0.40		
St.Dev	10.10	8.92	9.53		
KWD	5.77	-5.77			
KWS	0.75				
KW P	0.3854				

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Table 2: Analysis of Confounding variables by Study  
 Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
 on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
 A meta-analysis of results from two randomized clinical trials

		Group		
		1 Active	2 Placebo	Total
<b>Fagerström Dependency Test</b>				
<b>Serbia</b>		N	158	161
<b>1</b>			2	4
<b>2</b>			4	7
<b>3</b>			12	12
<b>4</b>			13	14
<b>5</b>			24	17
<b>6</b>			30	30
<b>7</b>			25	33
<b>8</b>			32	21
<b>9</b>			8	16
<b>10</b>			8	7
				319
				6
				11
				24
				27
				41
				60
				58
				53
				24
				15
<b>USA</b>		N	125	125
<b>none</b>			3	0
<b>1</b>			2	0
<b>2</b>			7	7
<b>3</b>			13	15
<b>4</b>			10	15
<b>5</b>			23	26
<b>6</b>			28	20
<b>7</b>			16	19
<b>8</b>			10	13
<b>9</b>			9	9
<b>10</b>			4	1
				250
				3
				2
				14
				28
				25
				49
				48
				35
				23
				18
				5
<b>Fagerström Dependency Test</b>				
<b>Serbia</b>		N	158	161
		Mean	6.21	6.14
		St.Err	0.16	0.17
		St.Dev	2.03	2.18
		Median	6.00	6.00
		Range	1:10	1:10
		Q25:75	5.00:8.00	5.00:8.00
		KWS	0.01	
		KW P	0.9106	
<b>USA</b>		N	125	125
		Mean	5.53	5.58
		St.Err	0.20	0.18
		St.Dev	2.24	1.96
		Median	6.00	5.00
		Range	0:10	2:10
		Q25:75	4.00:7.00	4.00:7.00
		KWS	0.00	
		KW P	0.9605	

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Table 2: Analysis of Confounding variables by Study  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>Fagerström Dependency Test</b>			
<b>Total</b>	N	283	286
	Mean	5.91	5.89
	St.Err	0.13	0.12
	St.Dev	2.15	2.11
	KWD	0.80	-0.80
	KWS	0.01	
	KW P	0.9070	

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Table 2: Analysis of Confounding variables by Study  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials

	N	Group		Total
		1 Active	2 Placebo	
<b>Previous quit attempt</b>				
<b>Serbia</b>				
Yes		158	161	319
		57	59	116
No		101	102	203
<b>USA</b>				
Yes		125	125	250
		112	107	219
No		13	18	31
<b>Previous quit attempt</b>				
<b>Yes</b>				
<b>Serbia</b>	n	57	59	116
	E	57.45	58.55	
	N	158	161	319
	%	36.08	36.65	36.36
	ChiSq	0.01		
	Chi P	0.9159		
	Ex P	1.0000		
<b>USA</b>	n	112	107	219
	E	109.50	109.50	
	N	125	125	250
	%	89.60	85.60	87.60
	ChiSq	0.92		
	Chi P	0.3383		
	Ex P	0.4432		
<b>Total</b>	n	169	166	335
	E	166.95	168.05	
	N	283	286	569
	%	59.72	58.04	58.88
	ChiSq	0.17		
	Chi P	0.6844		
	Ex P			

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Table 2: Analysis of Confounding variables by Study  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials

	N	Group		Total
		1 Active	2 Placebo	
<b>Previous exposure to NRT</b>				
<b>Serbia</b>				
Yes		158	161	319
No		1	2	3
		157	159	316
<b>USA</b>				
Yes		125	125	250
No		69	57	126
		56	68	124
<b>Previous exposure to NRT</b>				
<b>Yes</b>				
<b>Serbia</b>	n	1	2	3
	E	1.49	1.51	
	N	158	161	319
	%	0.63	1.24	0.94
	ChiSq	0.32		
	Chi P	0.5735		
	Ex P	1.0000		
<b>USA</b>	n	69	57	126
	E	63.00	63.00	
	N	125	125	250
	%	55.20	45.60	50.40
	ChiSq	2.29		
	Chi P	0.1298		
	Ex P	0.1640		
<b>Total</b>	n	70	59	129
	E	64.49	64.51	
	N	283	286	569
	%	24.73	20.63	22.67
	ChiSq	1.85		
	Chi P	0.1737		
	Ex P			

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Table 3: Analysis of Main Outcomes by Study  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>Primary: Smoking cessation weeks 6-</b>			
<b>28(USA) 25-48(Serbia)</b>			
Yes			
<b>Serbia</b>			
n	9	3	12
E	5.94	6.06	
N	158	161	319
%	5.70	1.86	3.76
ChiSq	3.23		
Chi P	0.0725 (+)		
Ex P	0.1297		
RR	3.06 (0.84,11.08)		
<b>USA</b>			
n	5	2	7
E	3.50	3.50	
N	125	125	250
%	4.00	1.60	2.80
ChiSq	1.32		
Chi P	0.2510		
Ex P	0.4465		
RR	2.50 (0.49,12.65)		
<b>Total</b>			
n	14	5	19
E	9.44	9.56	
N	283	286	569
%	4.95	1.75	3.34
ChiSq	4.51		
Chi P	0.0337 +		
Ex P	0.0559 (+)		
RR	2.83 (1.03,7.75)		
RR P	0.8490		

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Table 3: Analysis of Main Outcomes by Study  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>Smoke-free week 6(USA) 24(Serbia)</b>			
Yes			
<b>Serbia</b>			
n	9	3	12
E	5.94	6.06	
N	158	161	319
%	5.70	1.86	3.76
ChiSq	3.23		
Chi P	0.0725 (+)		
Ex P	0.1297		
RR	3.06 (0.84,11.08)		
<b>USA</b>			
n	23	11	34
E	17.00	17.00	
N	125	125	250
%	18.40	8.80	13.60
ChiSq	4.88		
Chi P	0.0271 +		
Ex P	0.0412 +		
RR	2.09 (1.07,4.10)		
<b>Total</b>			
n	32	14	46
E	22.94	23.06	
N	283	286	569
%	11.31	4.90	8.08
ChiSq	7.99		
Chi P	0.0047 ++		
Ex P	0.0070 ++		
RR	2.27 (1.25,4.12)		
RR P	0.6086		

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Table 3: Analysis of Main Outcomes by Study  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>Smoke-free week 16(USA) 36(Serbia)</b>			
Yes			
<b>Serbia</b>			
n	15	6	21
E	10.40	10.60	
N	158	161	319
%	9.49	3.73	6.58
ChiSq	4.30		
Chi P	0.0381 +		
Ex P	0.0621 (+)		
RR	2.55 (1.01,6.40)		
<b>USA</b>			
n	22	10	32
E	16.00	16.00	
N	125	125	250
%	17.60	8.00	12.80
ChiSq	5.14		
Chi P	0.0234 +		
Ex P	0.0360 +		
RR	2.20 (1.09,4.45)		
<b>Total</b>			
n	37	16	53
E	26.40	26.60	
N	283	286	569
%	13.07	5.59	9.31
ChiSq	9.42		
Chi P	0.0021 ++		
Ex P	0.0031 ++		
RR	2.32 (1.33,4.07)		
RR P	0.8043		

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Table 3: Analysis of Main Outcomes by Study  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>Smoke-free week 28(USA) 48(Serbia)</b>			
Yes			
<b>Serbia</b>			
n	25	15	40
E	19.81	20.19	
N	158	161	319
%	15.82	9.32	12.54
ChiSq	3.07		
Chi P	0.0798 (+)		
Ex P	0.1122		
RR	1.70 (0.93,3.10)		
<b>USA</b>			
n	16	9	25
E	12.50	12.50	
N	125	125	250
%	12.80	7.20	10.00
ChiSq	2.17		
Chi P	0.1408		
Ex P	0.2052		
RR	1.78 (0.82,3.87)		
<b>Total</b>			
n	41	24	65
E	32.31	32.69	
N	283	286	569
%	14.49	8.39	11.42
ChiSq	5.23		
Chi P	0.0221 +		
Ex P	0.0303 +		
RR	1.73 (1.07,2.78)		
RR P	0.9274		

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Table 3: Analysis of Main Outcomes by Study  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>Smoking cessation weeks 25-28(USA) 45-48(Serbia)</b>			
Yes			
<b>Serbia</b>			
n	22	12	34
E	16.84	17.16	
N	158	161	319
%	13.92	7.45	10.66
ChiSq	3.50		
Chi P	0.0615 (+)		
Ex P	0.0898 (+)		
RR	1.87 (0.96,3.64)		
<b>USA</b>			
n	13	7	20
E	10.00	10.00	
N	125	125	250
%	10.40	5.60	8.00
ChiSq	1.95		
Chi P	0.1627		
Ex P	0.2433		
RR	1.86 (0.77,4.50)		
<b>Total</b>			
n	35	19	54
E	26.84	27.16	
N	283	286	569
%	12.37	6.64	9.49
ChiSq	5.44		
Chi P	0.0197 +		
Ex P	0.0277 +		
RR	1.86 (1.09,3.18)		
RR P	0.9917		

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Table 3: Analysis of Main Outcomes by Study  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group			Total	
	1 Active	2 Placebo			
<b>Smoking cessation weeks 17-28(USA) 37-48(Serbia)</b>					
Yes					
<b>Serbia</b>	n	15	6	21	
	E	10.40	10.60		
	N	158	161	319	
	%	9.49	3.73	6.58	
	ChiSq	4.30			
	Chi P	0.0381 +			
	Ex P	0.0621 (+)			
	RR	2.55 (1.01,6.40)			
<b>USA</b>	n	12	6	18	
	E	9.00	9.00		
	N	125	125	250	
	%	9.60	4.80	7.20	
	ChiSq	2.15			
	Chi P	0.1429			
	Ex P	0.2204			
	RR	2.00 (0.77,5.16)			
<b>Total</b>	n	27	12	39	
	E	19.40	19.60		
	N	283	286	569	
	%	9.54	4.20	6.85	
	ChiSq	6.34			
	Chi P	0.0118 +			
	Ex P	0.0176 +			
	RR	2.27 (1.17,4.39)			
	RR P	0.7198			

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Table 4: Analysis of Main Outcomes by Study Site  
 Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
 on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
 A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>Primary: Smoking cessation weeks 6-28(USA) 25-48(Serbia)</b>			
Yes			
<b>Serbia_01</b>			
n	1	0	1
E	0.49	0.51	
N	46	47	93
%	2.17	0.00	1.08
ChiSq	1.02		
Chi P	0.3121		
Ex P	0.9892		
RR	3.06 (0.13,73.32)		
<b>Serbia_02</b>			
n	8	3	11
E	5.45	5.55	
N	112	114	226
%	7.14	2.63	4.87
ChiSq	2.47		
Chi P	0.1159		
Ex P	0.2039		
RR	2.71 (0.74,9.97)		
<b>US_CDE_001</b>			
n	1	0	1
E	0.51	0.49	
N	19	18	37
%	5.26	0.00	2.70
ChiSq	0.95		
Chi P	0.3304		
Ex P	1.0000		
RR	2.85 (0.12,65.74)		
<b>US_CD_001</b>			
n	1	0	1
E	0.50	0.50	
N	14	14	28
%	7.14	0.00	3.57
ChiSq	1.00		
Chi P	0.3173		
Ex P	1.0000		
RR	3.00 (0.13,67.91)		
<b>US_CP_001</b>			
n	0	2	2
E	1.00	1.00	
N	16	16	32
%	0.00	12.50	6.25
ChiSq	2.07		
Chi P	0.1506		
Ex P	0.4839		
RR	0.20 (0.01,3.86)		
<b>US_L0689282_2</b>			
n	0	0	0
N	16	16	32

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Table 4: Analysis of Main Outcomes by Study Site  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group			
	1 Active	2 Placebo	Total	
<b>US_P3880_0342</b>	n E N % ChiSq Chi P Ex P RR (0.38,134.85)	3 1.49 60 5.00 3.10 0.0782 (+) 0.2377 7.11 (0.38,134.85)	0 1.51 61 0.00 121 2.48	3
<b>Total</b>	n E N % ChiSq Chi P Ex P RR RR P	14 9.45 283 4.95 4.51 0.0337 + 0.0560 (+) 2.36 (0.92,6.05) 0.6513	5 9.55 286 1.75 19 569 3.34	

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Table 4: Analysis of Main Outcomes by Study Site  
 Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
 on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
 A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>Smoke-free week 6(USA) 24(Serbia)</b>			
Yes			
<b>Serbia 01</b>			
n	2	0	2
E	0.99	1.01	
N	46	47	93
%	4.35	0.00	2.15
ChiSq	2.07		
Chi P	0.1506		
Ex P	0.4839		
RR	5.11		
	(0.25,103.55)		
<b>Serbia 02</b>			
n	7	3	10
E	4.96	5.04	
N	112	114	226
%	6.25	2.63	4.42
ChiSq	1.74		
Chi P	0.1870		
Ex P	0.3183		
RR	2.38 (0.63,8.95)		
<b>US CDE_001</b>			
n	3	2	5
E	2.57	2.43	
N	19	18	37
%	15.79	11.11	13.51
ChiSq	0.17		
Chi P	0.6815		
Ex P	1.0000		
RR	1.42 (0.27,7.54)		
<b>US CD_001</b>			
n	2	0	2
E	1.00	1.00	
N	14	14	28
%	14.29	0.00	7.14
ChiSq	2.08		
Chi P	0.1495		
Ex P	0.4815		
RR	5.00 (0.26,95.61)		
<b>US CP_001</b>			
n	4	4	8
E	4.00	4.00	
N	16	16	32
%	25.00	25.00	25.00
ChiSq	0.00		
Chi P	1.0000		
Ex P	1.0000		
RR	1.00 (0.30,3.32)		

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Table 4: Analysis of Main Outcomes by Study Site  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>US_L0689282_2</b>	n E N % ChiSq Chi P Ex P RR	5 3.00 16 31.25 3.18 0.0746 (+) 0.1719 5.00 (0.66,38.15)	1 3.00 16 6.25 6
<b>US_P3880_0342</b>	n E N % ChiSq Chi P Ex P RR	9 6.45 60 15.00 2.23 0.1354 0.2272 2.29 (0.74,7.03)	4 6.55 61 6.56 13
<b>Total</b>	n E N % ChiSq Chi P Ex P RR RR P	32 22.96 283 11.31 8.00 0.0047 ++ 0.0069 ++ 2.02 (1.12,3.64) 0.7982	14 23.04 286 4.90 46 569 8.08

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Table 4: Analysis of Main Outcomes by Study Site  
 Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
 on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
 A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>Smoke-free week 16(USA) 36(Serbia)</b>			
Yes			
<b>Serbia 01</b>			
n	2	0	2
E	0.99	1.01	
N	46	47	93
%	4.35	0.00	2.15
ChiSq	2.07		
Chi P	0.1506		
Ex P	0.4839		
RR	5.11		
	(0.25,103.55)		
<b>Serbia 02</b>			
n	13	6	19
E	9.42	9.58	
N	112	114	226
%	11.61	5.26	8.41
ChiSq	2.94		
Chi P	0.0864 (+)		
Ex P	0.1378		
RR	2.21 (0.87,5.60)		
<b>US CDE_001</b>			
n	3	1	4
E	2.05	1.95	
N	19	18	37
%	15.79	5.56	10.81
ChiSq	0.98		
Chi P	0.3230		
Ex P	0.6456		
RR	2.84 (0.32,24.88)		
<b>US CD_001</b>			
n	2	0	2
E	1.00	1.00	
N	14	14	28
%	14.29	0.00	7.14
ChiSq	2.08		
Chi P	0.1495		
Ex P	0.4815		
RR	5.00 (0.26,95.61)		
<b>US CP_001</b>			
n	4	3	7
E	3.50	3.50	
N	16	16	32
%	25.00	18.75	21.88
ChiSq	0.18		
Chi P	0.6738		
Ex P	1.0000		
RR	1.33 (0.35,5.03)		

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Table 4: Analysis of Main Outcomes by Study Site  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group			
	1 Active	2 Placebo	Total	
<b>US_L0689282_2</b>	n E N % ChiSq Chi P Ex P RR	2 2.50 16 12.50 0.23 0.6318 1.0000 0.67 (0.13,3.47)	3 2.50 16 18.75 3 32 15.63	5
<b>US_P3880_0342</b>	n E N % ChiSq Chi P Ex P RR	11 6.94 60 18.33 5.28 0.0216 + 0.0402 + 3.73 (1.09,12.70)	3 7.06 61 4.92 3 121 11.57	14
<b>Total</b>	n E N % ChiSq Chi P Ex P RR RR P	37 26.40 283 13.07 9.45 0.0021 ++ 0.0031 ++ 2.11 (1.21,3.70) 0.6899	16 26.60 286 5.59 16 569 9.31	53

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Table 4: Analysis of Main Outcomes by Study Site  
 Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
 on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
 A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>Smoke-free week 28(USA) 48(Serbia)</b>			
Yes			
<b>Serbia 01</b>			
n	2	1	3
E	1.48	1.52	
N	46	47	93
%	4.35	2.13	3.23
ChiSq	0.36		
Chi P	0.5468		
Ex P	0.9837		
RR	2.04 (0.19,21.77)		
<b>Serbia 02</b>			
n	23	14	37
E	18.34	18.66	
N	112	114	226
%	20.54	12.28	16.37
ChiSq	2.80		
Chi P	0.0943 (+)		
Ex P	0.1337		
RR	1.67 (0.91,3.08)		
<b>US CDE_001</b>			
n	3	0	3
E	1.54	1.46	
N	19	18	37
%	15.79	0.00	8.11
ChiSq	3.01		
Chi P	0.0828 (+)		
Ex P	0.2494		
RR	6.65 (0.37,120.36)		
<b>US CD_001</b>			
n	1	0	1
E	0.50	0.50	
N	14	14	28
%	7.14	0.00	3.57
ChiSq	1.00		
Chi P	0.3173		
Ex P	1.0000		
RR	3.00 (0.13,67.91)		
<b>US CP_001</b>			
n	3	3	6
E	3.00	3.00	
N	16	16	32
%	18.75	18.75	18.75
ChiSq	0.00		
Chi P	1.0000		
Ex P	1.0000		
RR	1.00 (0.24,4.23)		

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Table 4: Analysis of Main Outcomes by Study Site  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group			
	1 Active	2 Placebo	Total	
<b>US_L0689282_2</b>	n E N % ChiSq Chi P Ex P RR	1 2.00 16 6.25 1.11 0.2927 0.5996 0.33 (0.04,2.87)	3 2.00 16 18.75 4 32 12.50	4
<b>US_P3880_0342</b>	n E N % ChiSq Chi P Ex P RR	8 5.45 60 13.33 2.57 0.1089 0.1944 2.71 (0.76,9.73)	3 5.55 61 4.92 4 121 9.09	11
<b>Total</b>	n E N % ChiSq Chi P Ex P RR RR P	41 32.32 283 14.49 5.33 0.0209 + 0.0288 + 1.66 (1.03,2.67) 0.6464	24 32.68 286 8.39 3 569 11.42	65

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Table 4: Analysis of Main Outcomes by Study Site  
 Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
 on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
 A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>Smoking cessation weeks 25-28(USA) 45-48(Serbia)</b>			
<b>Yes</b>			
<b>Serbia 01</b>			
n	2	0	2
E	0.99	1.01	
N	46	47	93
%	4.35	0.00	2.15
ChiSq	2.07		
Chi P	0.1506		
Ex P	0.4839		
RR	5.11		
	(0.25,103.55)		
<b>Serbia 02</b>			
n	20	12	32
E	15.86	16.14	
N	112	114	226
%	17.86	10.53	14.16
ChiSq	2.49		
Chi P	0.1148		
Ex P	0.1640		
RR	1.70 (0.87,3.30)		
<b>US CDE_001</b>			
n	1	0	1
E	0.51	0.49	
N	19	18	37
%	5.26	0.00	2.70
ChiSq	0.95		
Chi P	0.3304		
Ex P	1.0000		
RR	2.85 (0.12,65.74)		
<b>US CD_001</b>			
n	1	0	1
E	0.50	0.50	
N	14	14	28
%	7.14	0.00	3.57
ChiSq	1.00		
Chi P	0.3173		
Ex P	1.0000		
RR	3.00 (0.13,67.91)		
<b>US CP_001</b>			
n	3	3	6
E	3.00	3.00	
N	16	16	32
%	18.75	18.75	18.75
ChiSq	0.00		
Chi P	1.0000		
Ex P	1.0000		
RR	1.00 (0.24,4.23)		

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Table 4: Analysis of Main Outcomes by Study Site  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group			
	1 Active	2 Placebo	Total	
<b>US_L0689282_2</b>	n E N % ChiSq Chi P Ex P RR	1 2.00 16 6.25 1.11 0.2927 0.5996 0.33 (0.04,2.87)	3 2.00 16 18.75 4 32 12.50	4
<b>US_P3880_0342</b>	n E N % ChiSq Chi P Ex P RR	7 3.97 60 11.67 4.88 0.0271 + 0.0581 (+) 7.12 (0.90,56.10)	1 4.03 61 1.64 8 121 6.61	
<b>Total</b>	n E N % ChiSq Chi P Ex P RR RR P	35 26.83 283 12.37 5.59 0.0180 + 0.0256 + 1.68 (0.98,2.87) 0.5052	19 27.17 286 6.64 54 569 9.49	

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Table 4: Analysis of Main Outcomes by Study Site  
 Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
 on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
 A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>Smoking cessation weeks 17-28(USA) 37-48(Serbia)</b>			
<b>Yes</b>			
<b>Serbia 01</b>			
n	2	0	2
E	0.99	1.01	
N	46	47	93
%	4.35	0.00	2.15
ChiSq	2.07		
Chi P	0.1506		
Ex P	0.4839		
RR	5.11		
	(0.25,103.55)		
<b>Serbia 02</b>			
n	13	6	19
E	9.42	9.58	
N	112	114	226
%	11.61	5.26	8.41
ChiSq	2.94		
Chi P	0.0864 (+)		
Ex P	0.1378		
RR	2.21 (0.87,5.60)		
<b>US CDE_001</b>			
n	1	0	1
E	0.51	0.49	
N	19	18	37
%	5.26	0.00	2.70
ChiSq	0.95		
Chi P	0.3304		
Ex P	1.0000		
RR	2.85 (0.12,65.74)		
<b>US CD_001</b>			
n	1	0	1
E	0.50	0.50	
N	14	14	28
%	7.14	0.00	3.57
ChiSq	1.00		
Chi P	0.3173		
Ex P	1.0000		
RR	3.00 (0.13,67.91)		
<b>US CP_001</b>			
n	3	3	6
E	3.00	3.00	
N	16	16	32
%	18.75	18.75	18.75
ChiSq	0.00		
Chi P	1.0000		
Ex P	1.0000		
RR	1.00 (0.24,4.23)		

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Table 4: Analysis of Main Outcomes by Study Site  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group			
	1 Active	2 Placebo	Total	
<b>US_L0689282_2</b>	n E N % ChiSq Chi P Ex P RR	1 2.00 16 6.25 1.11 0.2927 0.5996 0.33 (0.04,2.87)	3 2.00 16 18.75 4 32 12.50	4
<b>US_P3880_0342</b>	n E N % ChiSq Chi P Ex P RR	6 2.98 60 10.00 6.37 0.0116 + 0.0261 + 13.21 (0.76,229.49)	0 3.02 61 0.00 121 4.96	6
<b>Total</b>	n E N % ChiSq Chi P Ex P RR RR P	27 19.39 283 9.54 6.45 0.0111 + 0.0166 + 1.84 (0.95,3.56) 0.4588	12 19.61 286 4.20 39 569 6.85	

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Table 5: a) Analysis of Main Outcomes by Sex  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>Primary: Smoking cessation weeks 6-</b>			
<b>28(USA) 25-48(Serbia)</b>			
Yes			
<b>Male</b>			
n	6	1	7
E	3.27	3.73	
N	103	118	221
%	5.83	0.85	3.17
ChiSq	4.40		
Chi P	0.0360 +		
Ex P	0.0823 (+)		
RR	4.64 (0.78,27.47)		
RR P	0.6077		
<b>Female</b>			
n	8	4	12
E	6.17	5.83	
N	180	168	348
%	4.44	2.38	3.45
ChiSq	1.15		
Chi P	0.2835		
Ex P	0.4375		
RR	1.81 (0.53,6.15)		
RR P	0.3418		
<b>Total</b>			
n	14	5	19
E	9.44	9.56	
N	283	286	569
%	4.95	1.75	3.34
ChiSq	4.52		
Chi P	0.0335 +		
Ex P	0.0556 (+)		
RR	2.45 (0.90,6.71)		
RR P	0.1687		

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Table 5: a) Analysis of Main Outcomes by Sex  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

		Group		Total		
		1 Active	2 Placebo			
<b>Smoke-free week 6(USA) 24(Serbia)</b>						
Yes						
<b>Male</b>						
n	11	7		18		
E	8.24	9.76				
N	103	118		221		
%	10.68	5.93		8.14		
ChiSq	1.90					
Chi P	0.1682					
Ex P	0.2578					
RR	1.75 (0.70,4.38)					
RR P	0.3630					
<b>Female</b>						
n	21	7		28		
E	14.73	13.27				
N	180	168		348		
%	11.67	4.17		8.05		
ChiSq	6.32					
Chi P	0.0120 +					
Ex P	0.0185 +					
RR	2.71 (1.19,6.15)					
RR P	0.8874					
<b>Total</b>						
n	32	14		46		
E	22.96	23.04				
N	283	286		569		
%	11.31	4.90		8.08		
ChiSq	7.97					
Chi P	0.0048 ++					
Ex P	0.0071 ++					
RR	2.23 (1.21,4.11)					
RR P	0.2485					

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Table 5: a) Analysis of Main Outcomes by Sex  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>Smoke-free week 16(USA) 36(Serbia)</b>			
Yes			
<b>Male</b>			
n	13	6	19
E	8.75	10.25	
N	103	118	221
%	12.62	5.08	8.60
ChiSq	4.22		
Chi P	0.0400 +		
Ex P	0.0688 (+)		
RR	2.48 (0.96,6.39)		
RR P	0.3387		
<b>Female</b>			
n	24	10	34
E	17.73	16.27	
N	180	168	348
%	13.33	5.95	9.77
ChiSq	5.16		
Chi P	0.0231 +		
Ex P	0.0344 +		
RR	2.10 (1.04,4.27)		
RR P	0.3057		
<b>Total</b>			
n	37	16	53
E	26.47	26.53	
N	283	286	569
%	13.07	5.59	9.31
ChiSq	9.30		
Chi P	0.0023 ++		
Ex P	0.0033 ++		
RR	2.23 (1.27,3.94)		
RR P	0.1533		

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Table 5: a) Analysis of Main Outcomes by Sex  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

		Group		Total		
		1 Active	2 Placebo			
<b>Smoke-free week 28(USA) 48(Serbia)</b>						
Yes						
<b>Male</b>						
n	14	9		23		
E	10.66	12.34				
N	103	118		221		
%	13.59	7.63		10.41		
ChiSq	2.16					
Chi P	0.1417					
Ex P	0.2107					
RR	1.80 (0.81,3.98)					
RR P	0.9025					
<b>Female</b>						
n	27	15		42		
E	21.58	20.42				
N	180	168		348		
%	15.00	8.93		12.07		
ChiSq	3.20					
Chi P	0.0735 (+)					
Ex P	0.1024					
RR	1.70 (0.94,3.07)					
RR P	0.7603					
<b>Total</b>						
n	41	24		65		
E	32.24	32.76				
N	283	286		569		
%	14.49	8.39		11.42		
ChiSq	5.35					
Chi P	0.0207 +					
Ex P	0.0285 +					
RR	1.73 (1.08,2.79)					
RR P	0.7277					

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Table 5: a) Analysis of Main Outcomes by Sex  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>Smoking cessation weeks 25-28(USA) 45-48(Serbia)</b>			
<b>Yes</b>			
<b>Male</b>			
n	11	7	18
E	8.36	9.64	
N	103	118	221
%	10.68	5.93	8.14
ChiSq	1.69		
Chi P	0.1942		
Ex P	0.2916		
RR	1.80 (0.72,4.50)		
RR P	0.7112		
<b>Female</b>			
n	24	12	36
E	18.49	17.51	
N	180	168	348
%	13.33	7.14	10.34
ChiSq	3.78		
Chi P	0.0519 (+)		
Ex P	0.0750 (+)		
RR	1.88 (0.97,3.64)		
RR P	0.7006		
<b>Total</b>			
n	35	19	54
E	26.85	27.15	
N	283	286	569
%	12.37	6.64	9.49
ChiSq	5.46		
Chi P	0.0195 +		
Ex P	0.0275 +		
RR	1.85 (1.09,3.17)		
RR P	0.5900		

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Table 5: a) Analysis of Main Outcomes by Sex  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>Smoking cessation weeks 17-28(USA) 37-48(Serbia)</b>			
<b>Yes</b>			
<b>Male</b>			
n	9	6	15
E	6.95	8.05	
N	103	118	221
%	8.74	5.08	6.79
ChiSq	1.20		
Chi P	0.2729		
Ex P	0.4059		
RR	1.74 (0.64,4.72)		
RR P	0.7343		
<b>Female</b>			
n	18	6	24
E	12.40	11.60	
N	180	168	348
%	10.00	3.57	6.90
ChiSq	5.59		
Chi P	0.0180 +		
Ex P	0.0285 +		
RR	2.75 (1.11,6.80)		
RR P	0.5420		
<b>Total</b>			
n	27	12	39
E	19.35	19.65	
N	283	286	569
%	9.54	4.20	6.85
ChiSq	6.43		
Chi P	0.0112 +		
Ex P	0.0168 +		
RR	2.24 (1.14,4.37)		
RR P	0.3335		

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Table 5: b) Analysis of Main Outcomes by Age  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

		Group		Total		
		1 Active	2 Placebo			
<b>Primary: Smoking cessation weeks 6-</b>						
<b>28(USA) 25-48(Serbia)</b>						
Yes						
<b>20-45</b>						
n	5	2		7		
E	3.59	3.41				
N	146	139		285		
%	3.42	1.44		2.46		
ChiSq	1.16					
Chi P	0.2810					
Ex P	0.4902					
RR	2.35 (0.46,12.00)					
RR P	0.7800					
<b>46-64</b>						
n	9	3		12		
E	5.79	6.21				
N	137	147		284		
%	6.57	2.04		4.23		
ChiSq	3.57					
Chi P	0.0588 (+)					
Ex P	0.1078					
RR	3.21 (0.89,11.61)					
RR P	0.9937					
<b>Total</b>						
n	14	5		19		
E	9.38	9.62				
N	283	286		569		
%	4.95	1.75		3.34		
ChiSq	4.64					
Chi P	0.0312 +					
Ex P	0.0521 (+)					
RR	2.85 (1.04,7.82)					
RR P	0.6843					

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Table 5: b) Analysis of Main Outcomes by Age  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

		Group		Total		
		1 Active	2 Placebo			
<b>Smoke-free week 6(USA) 24(Serbia)</b>						
Yes						
<b>20-45</b>						
n	17	8		25		
E	12.97	12.03				
N	146	139		285		
%	11.64	5.76		8.77		
ChiSq	3.05					
Chi P	0.0806 (+)					
Ex P	0.1230					
RR	1.95 (0.89,4.25)					
RR P	0.7030					
<b>46-64</b>						
n	15	6		21		
E	10.12	10.88				
N	137	147		284		
%	10.95	4.08		7.39		
ChiSq	4.91					
Chi P	0.0268 +					
Ex P	0.0449 +					
RR	2.67 (1.07,6.66)					
RR P	0.7789					
<b>Total</b>						
n	32	14		46		
E	23.09	22.91				
N	283	286		569		
%	11.31	4.90		8.08		
ChiSq	7.80					
Chi P	0.0052 ++					
Ex P	0.0077 ++					
RR	2.22 (1.23,4.03)					
RR P	0.4842					

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Table 5: b) Analysis of Main Outcomes by Age  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

		Group		Total		
		1 Active	2 Placebo			
<b>Smoke-free week 16(USA) 36(Serbia)</b>						
Yes						
<b>20-45</b>						
n	18	10		28		
E	14.44	13.56				
N	146	139		285		
%	12.33	7.19		9.82		
ChiSq	2.04					
Chi P	0.1529					
Ex P	0.2174					
RR	1.66 (0.80,3.45)					
RR P	0.5729					
<b>46-64</b>						
n	19	6		25		
E	12.05	12.95				
N	137	147		284		
%	13.87	4.08		8.80		
ChiSq	8.45					
Chi P	0.0037 ++					
Ex P	0.0062 ++					
RR	3.38 (1.39,8.23)					
RR P	0.7170					
<b>Total</b>						
n	37	16		53		
E	26.49	26.51				
N	283	286		569		
%	13.07	5.59		9.31		
ChiSq	9.26					
Chi P	0.0023 ++					
Ex P	0.0034 ++					
RR	2.21 (1.26,3.89)					
RR P	0.1663					

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Table 5: b) Analysis of Main Outcomes by Age  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

		Group		Total		
		1 Active	2 Placebo			
<b>Smoke-free week 28(USA) 48(Serbia)</b>						
Yes						
<b>20-45</b>						
n	18	12		30		
E	15.36	14.64				
N	146	139		285		
%	12.33	8.63		10.53		
ChiSq	1.03					
Chi P	0.3097					
Ex P	0.4101					
RR	1.43 (0.71,2.86)					
RR P	0.8075					
<b>46-64</b>						
n	23	12		35		
E	16.89	18.11				
N	137	147		284		
%	16.79	8.16		12.32		
ChiSq	4.86					
Chi P	0.0275 +					
Ex P	0.0420 +					
RR	2.04 (1.06,3.94)					
RR P	0.7109					
<b>Total</b>						
n	41	24		65		
E	32.25	32.75				
N	283	286		569		
%	14.49	8.39		11.42		
ChiSq	5.30					
Chi P	0.0213 +					
Ex P	0.0292 +					
RR	1.72 (1.07,2.78)					
RR P	0.3915					

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Table 5: b) Analysis of Main Outcomes by Age  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

		Group		Total		
		1 Active	2 Placebo			
<b>Smoking cessation weeks 25-28(USA) 45-48(Serbia)</b>						
Yes						
<b>20-45</b>	n	17	11	28		
E	14.33	13.67				
N	146	139	285			
%	11.64	7.91	9.82			
ChiSq	1.12					
Chi P	0.2900					
Ex P	0.3897					
RR	1.47 (0.71,3.03)					
RR P	0.5204					
<b>46-64</b>	n	18	8	26		
E	12.55	13.45				
N	137	147	284			
%	13.14	5.44	9.15			
ChiSq	5.03					
Chi P	0.0249 +					
Ex P	0.0402 +					
RR	2.34 (1.05,5.23)					
RR P	0.4740					
<b>Total</b>	n	35	19	54		
E	26.88	27.12				
N	283	286	569			
%	12.37	6.64	9.49			
ChiSq	5.37					
Chi P	0.0204 +					
Ex P	0.0287 +					
RR	1.81 (1.06,3.10)					
RR P	0.1993					

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Table 5: b) Analysis of Main Outcomes by Age  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

		Group		Total		
		1 Active	2 Placebo			
<b>Smoking cessation weeks 17-28(USA) 37-48(Serbia)</b>						
<b>Yes</b>						
<b>20-45</b>	n	14	8	22		
	E	11.30	10.70			
	N	146	139	285		
	%	9.59	5.76	7.72		
	ChiSq	1.43				
	Chi P	0.2312				
	Ex P	0.3286				
	RR	1.60 (0.68,3.75)				
	RR P	0.3270				
<b>46-64</b>	n	13	4	17		
	E	8.20	8.80			
	N	137	147	284		
	%	9.49	2.72	5.99		
	ChiSq	5.73				
	Chi P	0.0167 +				
	Ex P	0.0297 +				
	RR	3.27 (1.07,9.94)				
	RR P	0.4481				
<b>Total</b>	n	27	12	39		
	E	19.50	19.50			
	N	283	286	569		
	%	9.54	4.20	6.85		
	ChiSq	6.17				
	Chi P	0.0130 +				
	Ex P	0.0193 +				
	RR	2.08 (1.06,4.10)				
	RR P	0.1116				

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Table 5: c) Analysis of Main Outcomes by Smoking Intensity  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>Primary: Smoking cessation weeks 6-</b>			
<b>28(USA) 25-48(Serbia)</b>			
Yes			
<b>Light (10-19)</b>			
n	5	4	9
E	4.70	4.30	
N	60	56	116
%	8.33	7.14	7.76
ChiSq	0.04		
Chi P	0.8361		
Ex P	1.0000		
RR	1.15 (0.33,4.01)		
RR P	0.7991		
<b>&gt; Light</b>			
n	9	1	10
E	4.92	5.08	
N	223	230	453
%	4.04	0.43	2.21
ChiSq	6.78		
Chi P	0.0092 ++		
Ex P	0.0177 +		
RR	6.52 (1.18,36.15)		
RR P	0.9383		
<b>Total</b>			
n	14	5	19
E	9.62	9.38	
N	283	286	569
%	4.95	1.75	3.34
ChiSq	4.25		
Chi P	0.0392 +		
Ex P	0.0646 (+)		
RR	2.10 (0.77,5.76)		
RR P	0.1040		

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Table 5: c) Analysis of Main Outcomes by Smoking Intensity  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group			
	1 Active	2 Placebo	Total	
<b>Smoke-free week 6(USA) 24(Serbia)</b>				
Yes				
<b>Light (10-19)</b>	n E N % ChiSq Chi P Ex P RR RR P	12 11.36 60 20.00 0.09 0.7627 0.9483 1.12 (0.53,2.39) 0.8243	10 10.64 56 17.86         	22 116 18.97
<b>&gt; Light</b>	n E N % ChiSq Chi P Ex P RR RR P	20 11.84 223 8.97 12.01 0.0005 +++ 0.0008 +++ 5.10 (1.79,14.56) 0.8324	4 12.16 230 1.74         	24 453 5.30
<b>Total</b>	n E N % ChiSq Chi P Ex P RR RR P	32 23.20 283 11.31 7.70 0.0055 ++ 0.0082 ++ 1.88 (1.02,3.48) 0.0205 *	14 22.80 286 4.90         	46 569 8.08

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Table 5: c) Analysis of Main Outcomes by Smoking Intensity  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

		Group		Total		
		1 Active	2 Placebo			
<b>Smoke-free week 16(USA) 36(Serbia)</b>						
Yes						
<b>Light (10-19)</b>	n	14	11	25		
	E	12.93	12.07			
	N	60	56	116		
	%	23.33	19.64	21.55		
	ChiSq	0.23				
	Chi P	0.6326				
	Ex P	0.8002				
	RR	1.19 (0.59,2.39)				
	RR P	0.9870				
<b>&gt; Light</b>	n	23	5	28		
	E	13.79	14.21			
	N	223	230	453		
	%	10.31	2.17	6.18		
	ChiSq	12.91				
	Chi P	0.0003 +++				
	Ex P	0.0005 +++				
	RR	4.66 (1.79,12.08)				
	RR P	0.6247				
<b>Total</b>	n	37	16	53		
	E	26.73	26.27			
	N	283	286	569		
	%	13.07	5.59	9.31		
	ChiSq	9.14				
	Chi P	0.0025 ++				
	Ex P	0.0036 ++				
	RR	1.92 (1.09,3.37)				
	RR P	0.0206 *				

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Table 5: c) Analysis of Main Outcomes by Smoking Intensity  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

		Group		Total		
		1 Active	2 Placebo			
<b>Smoke-free week 28(USA) 48(Serbia)</b>						
Yes						
<b>Light (10-19)</b>	n	14	11	25		
	E	13.03	11.97			
	N	60	56	116		
	%	23.33	19.64	21.55		
	ChiSq	0.20				
	Chi P	0.6547				
	Ex P	0.8290				
	RR	1.12 (0.57,2.19)				
	RR P	0.4318				
<b>&gt; Light</b>	n	27	13	40		
	E	19.68	20.32			
	N	223	230	453		
	%	12.11	5.65	8.83		
	ChiSq	5.86				
	Chi P	0.0155 +				
	Ex P	0.0231 +				
	RR	2.14 (1.14,4.05)				
	RR P	0.9270				
<b>Total</b>	n	41	24	65		
	E	32.71	32.29			
	N	283	286	569		
	%	14.49	8.39	11.42		
	ChiSq	4.96				
	Chi P	0.0259 +				
	Ex P	0.0356 +				
	RR	1.58 (0.99,2.51)				
	RR P	0.1115				

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Table 5: c) Analysis of Main Outcomes by Smoking Intensity  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	n	Group		Total		
		1 Active	2 Placebo			
<b>Smoking cessation weeks 25-28(USA) 45-48(Serbia)</b>						
Yes						
<b>Light (10-19)</b>	n	11	8	19		
E	9.90	9.10				
N	60	56	116			
%	18.33	14.29	16.38			
ChiSq	0.31					
Chi P	0.5772					
Ex P	0.7621					
RR	1.25 (0.55,2.81)					
RR P	0.7550					
<b>&gt; Light</b>	n	24	11	35		
E	17.22	17.78				
N	223	230	453			
%	10.76	4.78	7.73			
ChiSq	5.68					
Chi P	0.0172 +					
Ex P	0.0261 +					
RR	2.25 (1.13,4.48)					
RR P	0.9164					
<b>Total</b>	n	35	19	54		
E	27.12	26.88				
N	283	286	569			
%	12.37	6.64	9.49			
ChiSq	5.18					
Chi P	0.0228 +					
Ex P	0.0321 +					
RR	1.76 (1.04,2.98)					
RR P	0.2560					

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Table 5: c) Analysis of Main Outcomes by Smoking Intensity  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	n	Group		Total		
		1 Active	2 Placebo			
<b>Smoking cessation weeks 17-28(USA) 37-48(Serbia)</b>						
Yes						
<b>Light (10-19)</b>	n	10	7	17		
E	8.84	8.16				
N	60	56	116			
%	16.67	12.50	14.66			
ChiSq	0.37					
Chi P	0.5421					
Ex P	0.7296					
RR	1.31 (0.54,3.18)					
RR P	0.8299					
<b>&gt; Light</b>	n	17	5	22		
E	10.83	11.17				
N	223	230	453			
%	7.62	2.17	4.86			
ChiSq	7.24					
Chi P	0.0071 ++					
Ex P	0.0118 +					
RR	3.50 (1.31,9.32)					
RR P	0.8368					
<b>Total</b>	n	27	12	39		
E	19.67	19.33				
N	283	286	569			
%	9.54	4.20	6.85			
ChiSq	6.05					
Chi P	0.0139 +					
Ex P	0.0207 +					
RR	2.04 (1.06,3.93)					
RR P	0.1375					

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Table 5: d) Analysis of Main Outcomes by Age Started Smoking  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>Primary: Smoking cessation weeks 6-</b>			
<b>28(USA) 25-48(Serbia)</b>			
Yes			
<b>&lt;18</b>			
n	5	2	7
E	3.43	3.57	
N	125	131	256
%	4.00	1.53	2.73
ChiSq	1.44		
Chi P	0.2297		
Ex P	0.4142		
RR	2.60 (0.51,13.23)		
RR P	0.8689		
<b>18+</b>			
n	9	3	12
E	6.08	5.92	
N	158	155	313
%	5.70	1.94	3.83
ChiSq	2.95		
Chi P	0.0859 (+)		
Ex P	0.1510		
RR	2.89 (0.79,10.57)		
RR P	0.7284		
<b>Total</b>			
n	14	5	19
E	9.51	9.49	
N	283	286	569
%	4.95	1.75	3.34
ChiSq	4.38		
Chi P	0.0363 +		
Ex P	0.0598 (+)		
RR	2.78 (1.01,7.65)		
RR P	0.6908		

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Table 5: d) Analysis of Main Outcomes by Age Started Smoking  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>Smoke-free week 6(USA) 24(Serbia)</b>			
<b>Yes</b>			
<b>&lt;18</b>			
n	16	7	23
E	11.49	11.51	
N	125	131	256
%	12.80	5.34	8.98
ChiSq	4.05		
Chi P	0.0441 +		
Ex P	0.0710 (+)		
RR	2.29 (0.99,5.30)		
RR P	0.9855		
<b>18+</b>			
n	16	7	23
E	11.53	11.47	
N	158	155	313
%	10.13	4.52	7.35
ChiSq	3.80		
Chi P	0.0513 (+)		
Ex P	0.0808 (+)		
RR	2.21 (0.94,5.20)		
RR P	0.5219		
<b>Total</b>			
n	32	14	46
E	23.02	22.98	
N	283	286	569
%	11.31	4.90	8.08
ChiSq	7.85		
Chi P	0.0051 ++		
Ex P	0.0075 ++		
RR	2.25 (1.24,4.10)		
RR P	0.5198		

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Table 5: d) Analysis of Main Outcomes by Age Started Smoking  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

		Group		Total		
		1 Active	2 Placebo			
<b>Smoke-free week 16(USA) 36(Serbia)</b>						
<b>Yes</b>						
<b>&lt;18</b>						
n	18	7		25		
E	12.40	12.60				
N	125	131		256		
%	14.40	5.34		9.77		
ChiSq	5.66					
Chi P	0.0173 +					
Ex P	0.0284 +					
RR	2.48 (1.08,5.71)					
RR P	0.4106					
<b>18+</b>						
n	19	9		28		
E	14.09	13.91				
N	158	155		313		
%	12.03	5.81		8.95		
ChiSq	3.77					
Chi P	0.0523 (+)					
Ex P	0.0792 (+)					
RR	2.08 (0.97,4.46)					
RR P	0.8216					
<b>Total</b>						
n	37	16		53		
E	26.49	26.51				
N	283	286		569		
%	13.07	5.59		9.31		
ChiSq	9.25					
Chi P	0.0024 ++					
Ex P	0.0034 ++					
RR	2.25 (1.29,3.95)					
RR P	0.3653					

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Table 5: d) Analysis of Main Outcomes by Age Started Smoking  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

		Group		Total		
		1 Active	2 Placebo			
<b>Smoke-free week 28(USA) 48(Serbia)</b>						
<b>Yes</b>						
<b>&lt;18</b>	n	17	12	29		
	E	14.18	14.82			
	N	125	131	256		
	%	13.60	9.16	11.33		
	ChiSq	1.23				
	Chi P	0.2680				
	Ex P	0.3615				
	RR	1.48 (0.73,2.98)				
	RR P	0.7524				
<b>18+</b>	n	24	12	36		
	E	18.23	17.77			
	N	158	155	313		
	%	15.19	7.74	11.50		
	ChiSq	4.18				
	Chi P	0.0408 +				
	Ex P	0.0600 (+)				
	RR	1.95 (1.01,3.75)				
	RR P	0.9411				
<b>Total</b>	n	41	24	65		
	E	32.42	32.58			
	N	283	286	569		
	%	14.49	8.39	11.42		
	ChiSq	5.11				
	Chi P	0.0238 +				
	Ex P	0.0325 +				
	RR	1.71 (1.06,2.76)				
	RR P	0.5163				

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Table 5: d) Analysis of Main Outcomes by Age Started Smoking  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

		Group		Total		
		1 Active	2 Placebo			
<b>Smoking cessation weeks 25-28(USA) 45-48(Serbia)</b>						
<b>Yes</b>						
<b>&lt;18</b>	n	14	9	23		
E		11.23	11.77			
N		125	131	256		
%		11.20	6.87	8.98		
ChiSq		1.46				
Chi P		0.2268				
Ex P		0.3209				
RR		1.63 (0.73,3.63)				
RR P		0.6663				
<b>18+</b>	n	21	10	31		
E		15.70	15.30			
N		158	155	313		
%		13.29	6.45	9.90		
ChiSq		4.03				
Chi P		0.0448 +				
Ex P		0.0671 (+)				
RR		2.02 (0.98,4.14)				
RR P		0.5559				
<b>Total</b>	n	35	19	54		
E		26.92	27.08			
N		283	286	569		
%		12.37	6.64	9.49		
ChiSq		5.33				
Chi P		0.0210 +				
Ex P		0.0295 +				
RR		1.83 (1.07,3.13)				
RR P		0.4079				

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Table 5: d) Analysis of Main Outcomes by Age Started Smoking  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

		Group		Total		
		1 Active	2 Placebo			
<b>Smoking cessation weeks 17-28(USA) 37-48(Serbia)</b>						
<b>Yes</b>						
<b>&lt;18</b>	n	11	6	17		
E		8.37	8.63			
N		125	131	256		
%		8.80	4.58	6.64		
ChiSq		1.74				
Chi P		0.1868				
Ex P		0.2839				
RR		1.68 (0.62,4.57)				
RR P		0.2040				
<b>18+</b>	n	16	6	22		
E		11.12	10.88			
N		158	155	313		
%		10.13	3.87	7.03		
ChiSq		4.63				
Chi P		0.0314 +				
Ex P		0.0506 (+)				
RR		2.42 (0.95,6.11)				
RR P		0.3304				
<b>Total</b>	n	27	12	39		
E		19.49	19.51			
N		283	286	569		
%		9.54	4.20	6.85		
ChiSq		6.19				
Chi P		0.0129 +				
Ex P		0.0191 +				
RR		2.04 (1.03,4.03)				
RR P		0.0922 (*)				

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Table 5: e) Analysis of Main Outcomes by Nicotene Dependence Score  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>Primary: Smoking cessation weeks 6-</b>			
<b>28(USA) 25-48(Serbia)</b>			
Yes			
<b>0-6</b>			
n	7	5	12
E	6.06	5.94	
N	171	167	338
%	4.09	2.99	3.55
ChiSq	0.31		
Chi P	0.5805		
Ex P	0.7974		
RR	1.37 (0.44,4.26)		
RR P	0.6610		
<b>7+</b>			
n	7	0	7
E	3.39	3.61	
N	112	119	231
%	6.25	0.00	3.03
ChiSq	7.62		
Chi P	0.0058 ++		
Ex P	0.0115 +		
RR	8.46 (1.07,66.58)		
RR P	0.9124		
<b>Total</b>			
n	14	5	19
E	9.45	9.55	
N	283	286	569
%	4.95	1.75	3.34
ChiSq	4.49		
Chi P	0.0340 +		
Ex P	0.0564 (+)		
RR	2.09 (0.77,5.65)		
RR P	0.1140		

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Table 5: e) Analysis of Main Outcomes by Nicotine Dependence Score  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

		Group		Total
		1 Active	2 Placebo	
<b>Smoke-free week 6(USA) 24(Serbia)</b>				
<b>Yes</b>				
<b>0-6</b>		n 20	n 11	n 31
		E 15.73	E 15.27	
		N 171	N 167	n 338
		% 11.70	% 6.59	n 9.17
		ChiSq 2.65		
		Chi P 0.1035		
		Ex P 0.1487		
		RR 1.77 (0.88,3.56)		
		RR P 0.6535		
<b>7+</b>		n 12	n 3	n 15
		E 7.25	E 7.75	
		N 112	N 119	n 231
		% 10.71	% 2.52	n 6.49
		ChiSq 6.58		
		Chi P 0.0103 +		
		Ex P 0.0192 +		
		RR 3.24 (1.00,10.42)		
		RR P 0.3413		
<b>Total</b>		n 32	n 14	n 46
		E 22.98	E 23.02	
		N 283	N 286	n 569
		% 11.31	% 4.90	n 8.08
		ChiSq 7.90		
		Chi P 0.0049 ++		
		Ex P 0.0073 ++		
		RR 2.07 (1.14,3.78)		
		RR P 0.1727		

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Table 5: e) Analysis of Main Outcomes by Nicotine Dependence Score  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

		Group		Total
		1 Active	2 Placebo	
<b>Smoke-free week 16(USA) 36(Serbia)</b>				
<b>Yes</b>				
<b>0-6</b>		n 24	n 12	n 36
		E 18.25	E 17.75	
		N 171	N 167	n 338
		% 14.04	% 7.19	n 10.65
		ChiSq 4.15		
		Chi P 0.0418 +		
		Ex P 0.0612 (+)		
		RR 1.94 (1.01,3.74)		
		RR P 0.9737		
<b>7+</b>		n 13	n 4	n 17
		E 8.23	E 8.77	
		N 112	N 119	n 231
		% 11.61	% 3.36	n 7.36
		ChiSq 5.76		
		Chi P 0.0164 +		
		Ex P 0.0294 +		
		RR 3.45 (1.16,10.26)		
		RR P 0.9044		
<b>Total</b>		n 37	n 16	n 53
		E 26.48	E 26.52	
		N 283	N 286	n 569
		% 13.07	% 5.59	n 9.31
		ChiSq 9.28		
		Chi P 0.0023 ++		
		Ex P 0.0034 ++		
		RR 2.27 (1.29,3.97)		
		RR P 0.3709		

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Table 5: e) Analysis of Main Outcomes by Nicotene Dependence Score  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

		Group		Total		
		1 Active	2 Placebo			
<b>Smoke-free week 28(USA) 48(Serbia)</b>						
<b>Yes</b>						
<b>0-6</b>	n	22	18	40		
	E	20.21	19.79			
	N	171	167	338		
	%	12.87	10.78	11.83		
	ChiSq	0.37				
	Chi P	0.5454				
	Ex P	0.6631				
	RR	1.20 (0.67,2.15)				
	RR P	0.8319				
<b>7+</b>	n	19	6	25		
	E	12.11	12.89			
	N	112	119	231		
	%	16.96	5.04	10.82		
	ChiSq	8.45				
	Chi P	0.0037 ++				
	Ex P	0.0062 ++				
	RR	3.34 (1.38,8.07)				
	RR P	0.6750				
<b>Total</b>	n	41	24	65		
	E	32.32	32.68			
	N	283	286	569		
	%	14.49	8.39	11.42		
	ChiSq	5.23				
	Chi P	0.0222 +				
	Ex P	0.0305 +				
	RR	1.64 (1.01,2.66)				
	RR P	0.0510 (*)				

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Table 5: e) Analysis of Main Outcomes by Nicotine Dependence Score  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	n	Group		Total		
		1 Active	2 Placebo			
<b>Smoking cessation weeks 25-28(USA) 45-48(Serbia)</b>						
<b>Yes</b>						
<b>0-6</b>	n	20	13	33		
	E	16.67	16.33			
	N	171	167	338		
	%	11.70	7.78	9.76		
	ChiSq	1.49				
	Chi P	0.2216				
	Ex P	0.2981				
	RR	1.51 (0.78,2.93)				
	RR P	0.8066				
<b>7+</b>	n	15	6	21		
	E	10.18	10.82			
	N	112	119	231		
	%	13.39	5.04	9.09		
	ChiSq	4.83				
	Chi P	0.0279 +				
	Ex P	0.0468 +				
	RR	2.64 (1.06,6.59)				
	RR P	0.7519				
<b>Total</b>	n	35	19	54		
	E	26.85	27.15			
	N	283	286	569		
	%	12.37	6.64	9.49		
	ChiSq	5.43				
	Chi P	0.0198 +				
	Ex P	0.0278 +				
	RR	1.83 (1.07,3.13)				
	RR P	0.2922				

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Table 5: e) Analysis of Main Outcomes by Nicotine Dependence Score  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

		Group		Total		
		1 Active	2 Placebo			
<b>Smoking cessation weeks 17-28(USA) 37-48(Serbia)</b>						
<b>Yes</b>						
<b>0-6</b>	n	15	8	23		
	E	11.63	11.37			
	N	171	167	338		
	%	8.77	4.79	6.80		
	ChiSq	2.11				
	Chi P	0.1460				
	Ex P	0.2141				
	RR	1.82 (0.79,4.20)				
	RR P	0.6156				
<b>7+</b>	n	12	4	16		
	E	7.75	8.25			
	N	112	119	231		
	%	10.71	3.36	6.93		
	ChiSq	4.86				
	Chi P	0.0275 +				
	Ex P	0.0491 +				
	RR	3.20 (1.07,9.59)				
	RR P	0.9852				
<b>Total</b>	n	27	12	39		
	E	19.37	19.63			
	N	283	286	569		
	%	9.54	4.20	6.85		
	ChiSq	6.39				
	Chi P	0.0115 +				
	Ex P	0.0172 +				
	RR	2.24 (1.15,4.36)				
	RR P	0.3458				

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Table 5: f) Analysis of Main Outcomes by Previous Quit Attempts  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>Primary: Smoking cessation weeks 6-</b>			
<b>28(USA) 25-48(Serbia)</b>			
<b>Yes</b>			
Yes	n	6	10
	E	5.01	4.99
	N	169	166
	%	3.55	2.41
	ChiSq	0.40	
	Chi P	0.5273	
	Ex P	0.7572	
	RR	1.49 (0.43,5.18)	
	RR P	0.9497	
<b>No</b>	n	8	9
	E	4.32	4.68
	N	114	120
	%	7.02	0.83
	ChiSq	6.24	
	Chi P	0.0125 +	
	Ex P	0.0262 +	
	RR	6.29 (1.14,34.85)	
	RR P	0.9512	
<b>Total</b>	n	14	19
	E	9.34	9.66
	N	283	286
	%	4.95	1.75
	ChiSq	4.73	
	Chi P	0.0297 +	
	Ex P	0.0497 +	
	RR	2.46 (0.90,6.72)	
	RR P	0.1816	

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Table 5: f) Analysis of Main Outcomes by Previous Quit Attempts  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>Smoke-free week 6(USA) 24(Serbia)</b>			
<b>Yes</b>			
Yes	n 24	13	37
	E 18.82	18.18	
	N 169	166	335
	% 14.20	7.83	11.04
	ChiSq 3.32		
	Chi P 0.0683 (+)		
	Ex P 0.0977 (+)		
	RR 1.79 (0.95,3.37)		
	RR P 0.8666		
<b>No</b>			
No	n 8	1	9
	E 4.32	4.68	
	N 114	120	234
	% 7.02	0.83	3.85
	ChiSq 6.24		
	Chi P 0.0125 +		
	Ex P 0.0262 +		
	RR 6.29 (1.14,34.85)		
	RR P 0.9512		
<b>Total</b>			
Total	n 32	14	46
	E 23.14	22.86	
	N 283	286	569
	% 11.31	4.90	8.08
	ChiSq 7.66		
	Chi P 0.0056 ++		
	Ex P 0.0083 ++		
	RR 2.08 (1.15,3.77)		
	RR P 0.1724		

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Table 5: f) Analysis of Main Outcomes by Previous Quit Attempts  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

		Group		Total
		1 Active	2 Placebo	
<b>Smoke-free week 16(USA) 36(Serbia)</b>				
<b>Yes</b>				
Yes	n	24	14	38
	E	19.25	18.75	
	N	169	166	335
	%	14.20	8.43	11.34
	ChiSq	2.68		
	Chi P	0.1017		
	Ex P	0.1415		
	RR	1.67 (0.89,3.12)		
	RR P	0.6480		
No	n	13	2	15
	E	7.23	7.77	
	N	114	120	234
	%	11.40	1.67	6.41
	ChiSq	9.47		
	Chi P	0.0021 ++		
	Ex P	0.0036 ++		
	RR	5.77 (1.53,21.73)		
	RR P	0.7027		
<b>Total</b>	n	37	16	53
	E	26.48	26.52	
	N	283	286	569
	%	13.07	5.59	9.31
	ChiSq	9.28		
	Chi P	0.0023 ++		
	Ex P	0.0034 ++		
	RR	2.09 (1.19,3.68)		
	RR P	0.0782 (*)		

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Table 5: f) Analysis of Main Outcomes by Previous Quit Attempts  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>Smoke-free week 28(USA) 48(Serbia)</b>			
<b>Yes</b>			
Yes	n 25	17	42
	E 21.10	20.90	
	N 169	166	335
	% 14.79	10.24	12.54
	ChiSq 1.66		
	Chi P 0.1977		
	Ex P 0.2605		
	RR 1.46 (0.82,2.59)		
	RR P 0.9414		
No	n 16	7	23
	E 11.29	11.71	
	N 114	120	234
	% 14.04	5.83	9.83
	ChiSq 4.27		
	Chi P 0.0388 +		
	Ex P 0.0626 (+)		
	RR 2.22 (0.97,5.10)		
	RR P 0.4407		
<b>Total</b>			
	n 41	24	65
	E 32.39	32.61	
	N 283	286	569
	% 14.49	8.39	11.42
	ChiSq 5.16		
	Chi P 0.0231 +		
	Ex P 0.0316 +		
	RR 1.67 (1.04,2.68)		
	RR P 0.2592		

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Table 5: f) Analysis of Main Outcomes by Previous Quit Attempts  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group			
	1 Active	2 Placebo	Total	
<b>Smoking cessation weeks 25-28(USA) 45-48(Serbia)</b>				
<b>Yes</b>				
Yes	n E N %	19 16.58 169 11.24	14 16.42 166 8.43	33 335 9.85
	ChiSq Chi P Ex P RR RR P	0.79 0.3742 0.4805 1.34 (0.69,2.58) 0.7221		
<b>No</b>				
No	n E N %	16 10.29 114 14.04	5 10.71 120 4.17	21 234 8.97
	ChiSq Chi P Ex P RR RR P	6.79 0.0092 ++ 0.0157 + 3.09 (1.21,7.84) 0.5819		
<b>Total</b>				
Total	n E N %	35 26.87 283 12.37	19 27.13 286 6.64	54 569 9.49
	ChiSq Chi P Ex P RR RR P	5.40 0.0201 + 0.0283 + 1.76 (1.03,3.02) 0.1148		

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Table 5: f) Analysis of Main Outcomes by Previous Quit Attempts  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>Smoking cessation weeks 17-28(USA) 37-48(Serbia)</b>			
<b>Yes</b>			
Yes	n E N %	15 12.61 169 8.88	10 12.39 166 6.02
	ChiSq Chi P Ex P RR RR P	0.99 0.3207 0.4320 1.47 (0.68,3.19) 0.7990	
No	n E N %	12 6.81 114 10.53	2 7.19 120 1.67
	ChiSq Chi P Ex P RR RR P	8.15 0.0043 ++ 0.0078 ++ 5.36 (1.41,20.33) 0.8612	
Total	n E N %	27 19.41 283 9.54	12 19.59 286 4.20
	ChiSq Chi P Ex P RR RR P	6.31 0.0120 + 0.0179 + 2.04 (1.05,3.98) 0.0945 (*)	

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Table 5: g) Analysis of Main Outcomes by Previous Use of NRT  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group			Total	
	1 Active	2 Placebo			
<b>Primary: Smoking cessation weeks 6-</b>					
<b>28(USA) 25-48(Serbia)</b>					
<b>Yes</b>					
Yes	n	2		4	
	E	2.19	1.81		
	N	70	59	129	
	%	2.86	3.39	3.10	
	ChiSq	0.04			
	Chi P	0.8464			
	Ex P	1.0000			
	RR	0.83 (0.12,5.68)			
<b>No</b>					
No	n	12	3	15	
	E	7.32	7.68		
	N	213	227	440	
	%	5.63	1.32	3.41	
	ChiSq	6.05			
	Chi P	0.0139 +			
	Ex P	0.0252 +			
	RR	3.58 (1.10,11.66)			
	RR P	0.5314			
<b>Total</b>					
Total	n	14	5	19	
	E	9.51	9.49		
	N	283	286	569	
	%	4.95	1.75	3.34	
	ChiSq	4.39			
	Chi P	0.0361 +			
	Ex P	0.0595 (+)			
	RR	2.40 (0.88,6.57)			
	RR P	0.1563			

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Table 5: g) Analysis of Main Outcomes by Previous Use of NRT  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

		Group		Total
		1 Active	2 Placebo	
<b>Smoke-free week 6(USA) 24(Serbia)</b>				
<b>Yes</b>				
Yes	n	14	7	21
	E	11.29	9.71	
	N	70	59	129
	%	20.00	11.86	16.28
	ChiSq	1.67		
	Chi P	0.1969		
	Ex P	0.2904		
	RR	1.70 (0.76,3.81)		
	RR P	0.4491		
No	n	18	7	25
	E	11.79	13.21	
	N	213	227	440
	%	8.45	3.08	5.68
	ChiSq	6.70		
	Chi P	0.0097 ++		
	Ex P	0.0163 +		
	RR	2.89 (1.24,6.72)		
	RR P	0.8935		
<b>Total</b>	n	32	14	46
	E	23.07	22.93	
	N	283	286	569
	%	11.31	4.90	8.08
	ChiSq	7.82		
	Chi P	0.0052 ++		
	Ex P	0.0077 ++		
	RR	2.19 (1.22,3.93)		
	RR P	0.2380		

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Table 5: g) Analysis of Main Outcomes by Previous Use of NRT  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group			
	1 Active	2 Placebo	Total	
<b>Smoke-free week 16(USA) 36(Serbia)</b>				
<b>Yes</b>				
Yes	n E N % ChiSq Chi P Ex P RR	10 8.21 70 14.29 0.97 0.3256 0.4807 1.65 (0.60,4.56)	5 6.79 59 8.47 11.63	15
No	n E N % ChiSq Chi P Ex P RR RR P	27 18.11 213 12.68 9.21 0.0024 ++ 0.0038 ++ 2.70 (1.38,5.29) 0.8377	11 19.89 227 4.85 38	440 8.64
<b>Total</b>	n E N % ChiSq Chi P Ex P RR RR P	37 26.33 283 13.07 9.59 0.0020 ++ 0.0028 ++ 2.33 (1.33,4.07) 0.4124	16 26.67 286 5.59 53	569 9.31

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Table 5: g) Analysis of Main Outcomes by Previous Use of NRT  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>Smoke-free week 28(USA) 48(Serbia)</b>			
<b>Yes</b>			
Yes	n 9 E 7.67 N 70 % 12.86 ChiSq 0.57 Chi P 0.4494 Ex P 0.6406 RR 1.49 (0.53,4.19)	5 6.33 59 8.47	14 129 10.85
No	n 32 E 24.84 N 213 % 15.02 ChiSq 4.55 Chi P 0.0329 + Ex P 0.0465 + RR 1.77 (1.04,3.02) RR P 0.7326	19 26.16 227 8.37	51 440 11.59
<b>Total</b>	n 41 E 32.51 N 283 % 14.49 ChiSq 5.02 Chi P 0.0251 + Ex P 0.0342 + RR 1.71 (1.06,2.75) RR P 0.6525	24 32.49 286 8.39	65 569 11.42

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Table 5: g) Analysis of Main Outcomes by Previous Use of NRT  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>Smoking cessation weeks 25-28(USA) 45-48(Serbia)</b>			
<b>Yes</b>			
Yes	n	7	11
	E	6.02	4.98
	N	70	59
	%	10.00	6.78
	ChiSq	0.38	
	Chi P	0.5375	
	Ex P	0.7703	
	RR	1.45 (0.45,4.69)	
No	n	28	43
	E	20.96	22.04
	N	213	227
	%	13.15	6.61
	ChiSq	5.12	
	Chi P	0.0237 +	
	Ex P	0.0347 +	
	RR	1.96 (1.08,3.56)	
	RR P	0.7252	
Total	n	35	54
	E	26.98	27.02
	N	283	286
	%	12.37	6.64
	ChiSq	5.27	
	Chi P	0.0217 +	
	Ex P	0.0304 +	
	RR	1.84 (1.08,3.14)	
	RR P	0.5676	

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Table 5: g) Analysis of Main Outcomes by Previous Use of NRT  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

	Group		
	1 Active	2 Placebo	Total
<b>Smoking cessation weeks 17-28(USA) 37-48(Serbia)</b>			
<b>Yes</b>			
Yes	n 6	4	10
	E 5.48	4.52	
	N 70	59	129
	% 8.57	6.78	7.75
	ChiSq 0.12		
	Chi P 0.7297		
	Ex P 0.9949		
	RR 1.24 (0.37,4.18)		
No	n 21	8	29
	E 14.05	14.95	
	N 213	227	440
	% 9.86	3.52	6.59
	ChiSq 7.13		
	Chi P 0.0076 ++		
	Ex P 0.0123 +		
	RR 2.78 (1.26,6.15)		
	RR P 0.6939		
Total	n 27	12	39
	E 19.52	19.48	
	N 283	286	569
	% 9.54	4.20	6.85
	ChiSq 6.15		
	Chi P 0.0131 +		
	Ex P 0.0195 +		
	RR 2.18 (1.12,4.24)		
	RR P 0.2458		

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Table 6: Analysis of Main Outcomes by Study  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials  
Compliant subjects only (Used product each day weeks 1-5 (USA), weeks 1-24 (Serbia))

	Group		
	1 Active	2 Placebo	Total
<b>Primary: Smoking cessation weeks 6-28(USA) 25-48(Serbia)</b>			
Yes			
<b>Serbia</b>			
n	7	3	10
E	4.78	5.22	
N	122	133	255
%	5.74	2.26	3.92
ChiSq	2.04		
Chi P	0.1532		
Ex P	0.2679		
RR	2.54 (0.67,9.62)		
<b>USA</b>			
n	5	1	6
E	2.97	3.03	
N	99	101	200
%	5.05	0.99	3.00
ChiSq	2.82		
Chi P	0.0932 (+)		
Ex P	0.2025		
RR	5.10 (0.61,42.88)		
<b>Total</b>			
n	12	4	16
E	7.75	8.25	
N	221	234	455
%	5.43	1.71	3.52
ChiSq	4.66		
Chi P	0.0309 +		
Ex P	0.0542 (+)		
RR	3.09 (1.00,9.55)		
RR P	0.5870		

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Table 6: Analysis of Main Outcomes by Study  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials  
Compliant subjects only (Used product each day weeks 1-5 (USA), weeks 1-24 (Serbia))

	Group		
	1 Active	2 Placebo	Total
<b>Smoke-free week 6(USA) 24(Serbia)</b>			
<b>Yes</b>			
<b>Serbia</b>			
n	6	3	9
E	4.31	4.69	
N	122	133	255
%	4.92	2.26	3.53
ChiSq	1.32		
Chi P	0.2507		
Ex P	0.4182		
RR	2.18 (0.56,8.53)		
<b>USA</b>			
n	22	10	32
E	15.84	16.16	
N	99	101	200
%	22.22	9.90	16.00
ChiSq	5.62		
Chi P	0.0178 +		
Ex P	0.0280 +		
RR	2.24 (1.12,4.49)		
<b>Total</b>			
n	28	13	41
E	20.15	20.85	
N	221	234	455
%	12.67	5.56	9.01
ChiSq	6.91		
Chi P	0.0086 ++		
Ex P	0.0131 +		
RR	2.23 (1.20,4.14)		
RR P	0.9704		

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Table 6: Analysis of Main Outcomes by Study  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials  
Compliant subjects only (Used product each day weeks 1-5 (USA), weeks 1-24 (Serbia))

	Group		
	1 Active	2 Placebo	Total
<b>Smoke-free week 16(USA) 36(Serbia)</b>			
Yes			
<b>Serbia</b>			
n	13	6	19
E	9.09	9.91	
N	122	133	255
%	10.66	4.51	7.45
ChiSq	3.47		
Chi P	0.0625 (+)		
Ex P	0.1025		
RR	2.36 (0.93,6.02)		
<b>USA</b>			
n	20	9	29
E	14.36	14.65	
N	99	101	200
%	20.20	8.91	14.50
ChiSq	5.12		
Chi P	0.0237 +		
Ex P	0.0376 +		
RR	2.27 (1.09,4.73)		
<b>Total</b>			
n	33	15	48
E	23.45	24.55	
N	221	234	455
%	14.93	6.41	10.55
ChiSq	8.58		
Chi P	0.0034 ++		
Ex P	0.0051 ++		
RR	2.30 (1.29,4.11)		
RR P	0.9462		

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Table 6: Analysis of Main Outcomes by Study  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials  
Compliant subjects only (Used product each day weeks 1-5 (USA), weeks 1-24 (Serbia))

	Group		
	1 Active	2 Placebo	Total
<b>Smoke-free week 28(USA) 48(Serbia)</b>			
Yes			
<b>Serbia</b>			
n	23	14	37
E	17.70	19.30	
N	122	133	255
%	18.85	10.53	14.51
ChiSq	3.54		
Chi P	0.0598 (+)		
Ex P	0.0873 (+)		
RR	1.79 (0.97,3.32)		
<b>USA</b>			
n	16	8	24
E	11.88	12.12	
N	99	101	200
%	16.16	7.92	12.00
ChiSq	3.20		
Chi P	0.0737 (+)		
Ex P	0.1139		
RR	2.04 (0.91,4.55)		
<b>Total</b>			
n	39	22	61
E	29.58	31.42	
N	221	234	455
%	17.65	9.40	13.41
ChiSq	6.70		
Chi P	0.0096 ++		
Ex P	0.0138 +		
RR	1.88 (1.15,3.07)		
RR P	0.8007		

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Table 6: Analysis of Main Outcomes by Study  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials  
Compliant subjects only (Used product each day weeks 1-5 (USA), weeks 1-24 (Serbia))

	n	Group		Total		
		1 Active	2 Placebo			
<b>Smoking cessation weeks 25-28(USA) 45-48(Serbia)</b>						
Yes						
<b>Serbia</b>						
n	20	12		32		
E	15.31	16.69				
N	122	133		255		
%	16.39	9.02		12.55		
ChiSq	3.14					
Chi P	0.0765 (+)					
Ex P	0.1125					
RR	1.82 (0.93,3.56)					
<b>USA</b>						
n	13	6		19		
E	9.41	9.60				
N	99	101		200		
%	13.13	5.94		9.50		
ChiSq	2.99					
Chi P	0.0837 (+)					
Ex P	0.1340					
RR	2.21 (0.87,5.58)					
<b>Total</b>						
n	33	18		51		
E	24.71	26.29				
N	221	234		455		
%	14.93	7.69		11.21		
ChiSq	6.06					
Chi P	0.0138 +					
Ex P	0.0201 +					
RR	1.94 (1.13,3.35)					
RR P	0.7372					

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	Group		
	1 Active	2 Placebo	Total
<b>Smoking cessation weeks 17-28(USA) 37-48(Serbia)</b>			
Yes			
<b>Serbia</b>			
n	13	6	19
E	9.09	9.91	
N	122	133	255
%	10.66	4.51	7.45
ChiSq	3.47		
Chi P	0.0625 (+)		
Ex P	0.1025		
RR	2.36 (0.93,6.02)		
<b>USA</b>			
n	12	5	17
E	8.42	8.59	
N	99	101	200
%	12.12	4.95	8.50
ChiSq	3.29		
Chi P	0.0698 (+)		
Ex P	0.1158		
RR	2.45 (0.90,6.69)		
<b>Total</b>			
n	25	11	36
E	17.51	18.49	
N	221	234	455
%	11.31	4.70	7.91
ChiSq	6.76		
Chi P	0.0093 ++		
Ex P	0.0144 +		
RR	2.40 (1.21,4.76)		
RR P	0.9591		

APPENDIX A

Structure of the linked databases

An identically structured ROELEE database was set up to contain the individual subject data from the two studies. The data are separated into “cards”, and into “fields” within cards. The attached listing shows, first for the US data, and then for the Serbian data, the names of the cards and fields and the type of information contained. This may be:

- Measured            Integer data within a specified range
- Real                Real data within a specified range and recorded to a specified number of decimal places
- Graded             Categorical data with the number of possible levels and their meanings defined by a grading system (see end of listing)
- Character          Text of up to a specified number of characters

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**Appendix A**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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 (US)

Card Name	Short Name	Position	Short Name	Number	Type
Field Name					
Demographics	DEMO (Page 1)	1	STUDYI	5	Character ( 20 )
Study Identifier			DOMAIN	6	Character ( 2 )
Domain Abbreviation			USUBJI	7	Character ( 50 )
Unique Subject Identifier			SUBJID	8	Character ( 20 )
Subject Identifier for the Study			RFSTDT	9	Character ( 50 )
Subject Reference Start Date/Time			RFENDT	10	Character ( 50 )
Subject Reference End Date/Time			SITEID	11	Character ( 10 )
Study Site Identifier			INVID	12	Character ( 20 )
Investigator Identifier			INVNAM	13	Character ( 50 )
Investigator Name			BRTHDT	14	Character ( 50 )
Date/Time of Birth			AGE	15	Real ( 0.00 to 99.00 )
Age			AGEU	16	Character ( 10 )
Age Units			V17	17	Character ( 2 )
Sex			RACE	18	Character ( 50 )
Race			ETHNIC	19	Character ( 25 )
Ethnicity			ARMCD	20	Character ( 20 )
Planned Arm Code			ARM	21	Character ( 200 )
Description of Planned Arm			COUNTR	22	Character ( 3 )
Country			DMDTC	23	Character ( 50 )
Date/Time of Collection			DMDY	24	Real ( -43.00 to 99.00 )
Study Day of Collection			DSTERM	25	Character ( 200 )
Reported Term for the Disposition Event			V26	26	Character ( 200 )
Reported Term for the Disposition Event			FSTAT	27	Character ( 200 )
Final Status			CO_W0	28	Real ( 0.00 to 99.00 )
COHb Week 0			CO_W6	29	Real ( 0.00 to 99.00 )
COHb Week 6			CO_W10	30	Real ( 0.00 to 99.00 )
COHb Week 10			CO_W16	31	Real ( 0.00 to 99.00 )
COHb Week 16			CO_W28	32	Real ( 0.00 to 99.00 )
COHb Week 28					
User Diary	UD6	2			
Week 6					
Not smoked cigarettes in past week			NOTSMK	36	Graded ( system 17 )
Cigarettes per day			CIGDY	222	Real ( 0.00 to 999.00 )
Smoked products other than cigarettes			SMKOTH	38	Graded ( system 2 )
Use smokeless tobacco/Nicotine/Smoking cessation products			UCESS	39	Graded ( system 2 )
Number large (1g)			NLARGE	40	Measured ( 0 to 999 )
Number small (0.5g)			NSMALL	41	Measured ( 0 to 999 )
Adverse Event			AE	42	Character ( 50 )
Adverse event related to snus			AEREL	43	Graded ( system 17 )

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**Appendix A**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")

on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials  
(US)

User Diary		UD7	3
User Diary		UD8	4
Week 7			
	Not smoked cigarettes in past week	NOTSMK	48
	Cigarettes per day	CIGDY	223
	Smoked products other than cigarettes	SMKOTH	50
	Use smokeless tobacco/Nicotine/Smoking cessation products	UCESS	51
	Number large (1g)	NLARGE	52
	Number small (0.5g)	NSMALL	53
	Adverse Event	AE	54
	Adverse event related to snus	AEREL	55
User Diary		UD9	5
Week 8			
	Not smoked cigarettes in past week	NOTSMK	60
	Cigarettes per day	CIGDY	224
	Smoked products other than cigarettes	SMKOTH	62
	Use smokeless tobacco/Nicotine/Smoking cessation products	UCESS	63
	Number large (1g)	NLARGE	64
	Number small (0.5g)	NSMALL	65
	Adverse Event	AE	66
	Adverse event related to snus	AEREL	67
User Diary		UD10	6
Week 9			
	Not smoked cigarettes in past week	NOTSMK	72
	Cigarettes per day	CIGDY	225
	Smoked products other than cigarettes	SMKOTH	74
	Use smokeless tobacco/Nicotine/Smoking cessation products	UCESS	75
	Number large (1g)	NLARGE	76
	Number small (0.5g)	NSMALL	77
	Adverse Event	AE	78
	Adverse event related to snus	AEREL	79
User Diary		UD11	7
Week 10			
	Not smoked cigarettes in past week	NOTSMK	84
	Cigarettes per day	CIGDY	226
	Smoked products other than cigarettes	SMKOTH	86
	Use smokeless tobacco/Nicotine/Smoking cessation products	UCESS	87
	Number large (1g)	NLARGE	88
	Number small (0.5g)	NSMALL	89
	Adverse Event	AE	90
	Adverse event related to snus	AEREL	91
User Diary			
Week 11			
	Not smoked cigarettes in past week	NOTSMK	96
	Cigarettes per day	CIGDY	227
	Smoked products other than cigarettes	SMKOTH	98
	Use smokeless tobacco/Nicotine/Smoking cessation products	UCESS	99
	Number large (1g)	NLARGE	100
	Number small (0.5g)	NSMALL	101
	Adverse Event	AE	102
	Adverse event related to snus	AEREL	103

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**Appendix A**

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A meta-analysis of results from two randomized clinical trials  
(US)

User Diary Week 12	UD12	8		
Not smoked cigarettes in past week	NOTSMK	108	Graded	( system 17 )
Cigarettes per day	CIGDY	228	Real	( 0.00 to 999.00 )
Smoked products other than cigarettes	SMKOTH	110	Graded	( system 2 )
Use smokeless tobacco/Nicotine/Smoking cessation products	UCESS	111	Graded	( system 2 )
Number large (1g)	NLARGE	112	Measured	( 0 to 999 )
Number small (0.5g)	NSMALL	113	Measured	( 0 to 999 )
Adverse Event	AE	114	Character	( 50 )
Adverse event related to snus	AEREL	115	Graded	( system 17 )
User Diary Week 13	UD13	9		
Not smoked cigarettes in past week	NOTSMK	120	Graded	( system 17 )
Cigarettes per day	CIGDY	229	Real	( 0.00 to 999.00 )
Smoked products other than cigarettes	SMKOTH	122	Graded	( system 2 )
Use smokeless tobacco/Nicotine/Smoking cessation products	UCESS	123	Graded	( system 2 )
Number large (1g)	NLARGE	124	Measured	( 0 to 999 )
Number small (0.5g)	NSMALL	125	Measured	( 0 to 999 )
Adverse Event	AE	126	Character	( 50 )
Adverse event related to snus	AEREL	127	Graded	( system 17 )
User Diary Week 14	UD14	10		
Not smoked cigarettes in past week	NOTSMK	132	Graded	( system 17 )
Cigarettes per day	CIGDY	230	Real	( 0.00 to 999.00 )
Smoked products other than cigarettes	SMKOTH	134	Graded	( system 2 )
Use smokeless tobacco/Nicotine/Smoking cessation products	UCESS	135	Graded	( system 2 )
Number large (1g)	NLARGE	136	Measured	( 0 to 999 )
Number small (0.5g)	NSMALL	137	Measured	( 0 to 999 )
Adverse Event	AE	138	Character	( 50 )
Adverse event related to snus	AEREL	139	Graded	( system 17 )
User Diary Week 15	UD15	11		
Not smoked cigarettes in past week	NOTSMK	144	Graded	( system 17 )
Cigarettes per day	CIGDY	231	Real	( 0.00 to 999.00 )
Smoked products other than cigarettes	SMKOTH	146	Graded	( system 2 )
Use smokeless tobacco/Nicotine/Smoking cessation products	UCESS	147	Graded	( system 2 )
Number large (1g)	NLARGE	148	Measured	( 0 to 999 )
Number small (0.5g)	NSMALL	149	Measured	( 0 to 999 )
Adverse Event	AE	150	Character	( 50 )
Adverse event related to snus	AEREL	151	Graded	( system 17 )
User Diary Week 16	UD16	12		
Not smoked cigarettes in past week	NOTSMK	160	Graded	( system 17 )
Cigarettes per day	CIGDY	232	Real	( 0.00 to 999.00 )
Smoked products other than cigarettes	SMKOTH	162	Graded	( system 2 )
Use smokeless tobacco/Nicotine/Smoking cessation products	UCESS	163	Graded	( system 2 )
Number large (1g)	NLARGE	164	Measured	( 0 to 999 )
Number small (0.5g)	NSMALL	165	Measured	( 0 to 999 )
Adverse Event	AE	166	Character	( 50 )
Adverse event related to snus	AEREL	167	Graded	( system 17 )

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**Appendix A**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials  
(US)

User Diary Week 17	UD17	13				
	Not smoked in past week		NOTSMK	173	Graded	( system 17 )
	Cigarettes per day		CIGDY	177	Real	( 0.00 to 999.00 )
	Smoked products other than cigarettes		SMKOTH	175	Graded	( system 2 )
	Used smokeless cessation products		UCESS	176	Character	( 50 )
User Diary Week 18	UD18	14				
	Not smoked cigarettes in past week		NOTSMK	233	Graded	( system 17 )
	Cigarettes per day		CIGDY	244	Real	( 0.00 to 999.00 )
	Smoked products other than cigarettes		SMKOTH	255	Graded	( system 2 )
	Used smokeless cessation products		UCESS	266	Character	( 50 )
User Diary Week 19	UD19	15				
	Not smoked cigarettes in past week		NOTSMK	234	Graded	( system 17 )
	Cigarettes per day		CIGDY	245	Real	( 0.00 to 999.00 )
	Smoked products other than cigarettes		SMKOTH	256	Graded	( system 2 )
	Used smokeless cessation products		UCESS	267	Character	( 50 )
User Diary Week 20	UD20	16				
	Not smoked cigarettes in past week		NOTSMK	235	Graded	( system 17 )
	Cigarettes per day		CIGDY	246	Real	( 0.00 to 999.00 )
	Smoked products other than cigarettes		SMKOTH	257	Graded	( system 2 )
	Used smokeless cessation products		UCESS	268	Character	( 50 )
User Diary Week 21	UD21	17				
	Not smoked cigarettes in past week		NOTSMK	236	Graded	( system 17 )
	Cigarettes per day		CIGDY	247	Real	( 0.00 to 999.00 )
	Smoked products other than cigarettes		SMKOTH	258	Graded	( system 2 )
	Used smokeless cessation products		UCESS	269	Character	( 50 )
User Diary Week 22	UD22	18				
	Not smoked cigarettes in past week		NOTSMK	237	Graded	( system 17 )
	Cigarettes per day		CIGDY	248	Real	( 0.00 to 999.00 )
	Smoked products other than cigarettes		SMKOTH	259	Graded	( system 2 )
	Used smokeless cessation products		UCESS	270	Character	( 50 )
User Diary Week 23	UD23	19				
	Not smoked cigarettes in past week		NOTSMK	238	Graded	( system 17 )
	Cigarettes per day		CIGDY	249	Real	( 0.00 to 999.00 )
	Smoked products other than cigarettes		SMKOTH	260	Graded	( system 2 )
	Used smokeless cessation products		UCESS	271	Character	( 50 )
User Diary Week 24	UD24	20				
	Not smoked cigarettes in past week		NOTSMK	239	Graded	( system 17 )
	Cigarettes per day		CIGDY	250	Real	( 0.00 to 999.00 )
	Smoked products other than cigarettes		SMKOTH	261	Graded	( system 2 )
	Used smokeless cessation products		UCESS	272	Character	( 50 )

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**Appendix A**

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A meta-analysis of results from two randomized clinical trials  
(US)

User Diary Week 25	UD25	21				
Not smoked cigarettes in past week			NOTSMK	240	Graded	( system 17 )
Cigarettes per day			CIGDY	251	Real	( 0.00 to 999.00 )
Smoked products other than cigarettes			SMKOTH	262	Graded	( system 2 )
Used smokeless cessation products			UCESS	273	Character	( 50 )
User Diary Week 26	UD26	22				
Not smoked cigarettes in past week			NOTSMK	241	Graded	( system 17 )
Cigarettes per day			CIGDY	252	Real	( 0.00 to 999.00 )
Smoked products other than cigarettes			SMKOTH	263	Graded	( system 2 )
Used smokeless cessation products			UCESS	274	Character	( 50 )
User Diary Week 27	UD27	23				
Not smoked cigarettes in past week			NOTSMK	242	Graded	( system 17 )
Cigarettes per day			CIGDY	253	Real	( 0.00 to 999.00 )
Smoked products other than cigarettes			SMKOTH	264	Graded	( system 2 )
Used smokeless cessation products			UCESS	275	Character	( 50 )
User Diary Week 28	UD28	24				
Not smoked cigarettes in past week			NOTSMK	243	Graded	( system 17 )
Cigarettes per day			CIGDY	254	Real	( 0.00 to 999.00 )
Smoked products other than cigarettes			SMKOTH	265	Graded	( system 2 )
Used smokeless cessation products			UCESS	276	Character	( 50 )
Expired Air CO (ppm)	ECO	25				
ECO week 0			ECO_0	278	Measured	( 0 to 9999 )
ECO week 6			ECO_6	279	Measured	( 0 to 9999 )
ECO week 10			ECO_10	280	Measured	( 0 to 9999 )
ECO week 16			ECO_16	281	Measured	( 0 to 9999 )
ECO week 28			ECO_28	282	Measured	( 0 to 9999 )
Fagerstrom Total Dependence	FAGTS	26				
Total dependence score Baseline			FTD_0	285	Measured	( 0 to 99 )
Total dependence score Week 16			FTD_16	286	Measured	( 0 to 99 )
Total dependence Week 28			FTD_28	287	Measured	( 0 to 99 )
Smoking History (at Screening)	SMHIST	27				
Age started smoking (years)			AGEST	290	Measured	( 1 to 99 )
Average Cigarettes per day (previous year)			CIGDAY	291	Measured	( 0 to 99 )
Use smokeless tobacco in the past			USEST	292	Graded	( system 2 )
Number times used NRT			NNRT	369	Character	( 20 )
Description of NRT used			NNRTD	370	Character	( 50 )
Number of other pharmaceuticals used to quit			NOTHP	371	Character	( 20 )
Description of other pharmaceuticals used			NOTHPD	372	Character	( 50 )
Number of times used other cessation aids			NOCA	373	Character	( 20 )
Description of other cessation aids used			NOCAD	374	Character	( 50 )
Number of times used other method to quit			NOMTH	375	Character	( 20 )
Description of other methods used			NOMTHD	376	Character	( 50 )

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**Appendix A**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials  
(US)

Outcomes	OUTCOM	28			
Primary Outcome: smoking cessation 6-28 (US) 25-48 (Serbia)	P_OUT	299	Graded	( system 2 )	
Smoke-free week 6 (US) week 24 (Serbia)	S_OUT1	301	Graded	( system 2 )	
Smoke-free week 16 (US) week 36 (Serbia)	S_OUT2	302	Graded	( system 2 )	
Smoke-free week 28 (US) week 48 (Serbia)	S_OUT3	303	Graded	( system 2 )	
Smoke-free weeks 25-28 (US) 45-48 (Serbia)	S_OUT4	367	Graded	( system 2 )	
Smoke-free weeks 17-28 (US) 37-48 (Serbia)	S_OUT5	368	Graded	( system 2 )	
Compliance	COMP	29			
Compliant (week 6)	COMP6	308	Graded	( system 2 )	
Compliant (week 8)	COMP8	309	Graded	( system 2 )	
Compliant (week 10)	COMP10	310	Graded	( system 2 )	
Compliant (week 13)	COMP13	311	Graded	( system 2 )	
Compliant (week 16)	COMP16	312	Graded	( system 2 )	
Compliant (week 20)	COMP20	313	Graded	( system 2 )	
Compliant (week 24)	COMP24	314	Graded	( system 2 )	
Compliant (week 28)	COMP28	315	Graded	( system 2 )	
User Diary Week 1	UD1	30			
Not smoked cigarettes in past week	NOTSMK	318	Graded	( system 17 )	
Cigarettes per day	CIGDY	319	Real	( 0.00 to 999.00 )	
Smoked products other than cigarettes	SMKOTH	320	Graded	( system 2 )	
Use smokeless tobacco/Nicotine/Smoking cessation products	UCESS	321	Graded	( system 2 )	
Number large (1g)	NLARGE	322	Measured	( 0 to 999 )	
Number small (0.5g)	NSMALL	323	Measured	( 0 to 999 )	
Adverse Event	AE	324	Character	( 50 )	
Adverse event related to snus	AEREL	325	Graded	( system 17 )	
User Diary Week 2	UD2	31			
Not smoked cigarettes in past week	NOTSMK	328	Graded	( system 17 )	
Cigarettes per day	CIGDY	329	Real	( 0.00 to 999.00 )	
Smoked products other than cigarettes	SMKOTH	330	Graded	( system 2 )	
Use smokeless tobacco/Nicotine/Smoking cessation products	UCESS	331	Graded	( system 2 )	
Number large (1g)	NLARGE	332	Measured	( 0 to 999 )	
Number small (0.5g)	NSMALL	333	Measured	( 0 to 999 )	
Adverse Event	AE	334	Character	( 50 )	
Adverse event related to snus	AEREL	335	Graded	( system 17 )	
User Diary Week 3	UD3	32			
Not smoked cigarettes in past week	NOTSMK	338	Graded	( system 17 )	
Cigarettes per day	CIGDY	339	Real	( 0.00 to 999.00 )	
Smoked products other than cigarettes	SMKOTH	340	Graded	( system 2 )	
Use smokeless tobacco/Nicotine/Smoking cessation products	UCESS	341	Graded	( system 2 )	
Number large (1g)	NLARGE	342	Measured	( 0 to 999 )	
Number small (0.5g)	NSMALL	343	Measured	( 0 to 999 )	
Adverse Event	AE	344	Character	( 50 )	
Adverse event related to snus	AEREL	345	Graded	( system 17 )	

**CONFIDENTIAL**

**Appendix A**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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(US)

User Diary Week 4	UD4 33	Not smoked cigarettes in past week Cigarettes per day Smoked products other than cigarettes Use smokeless tobacco/Nicotine/Smoking cessation products Number large (1g) Number small (0.5g) Adverse Event Adverse event related to snus	NOTSMK 348 Graded ( system 17 ) CIGDY 349 Real ( 0.00 to 999.00 ) SMKOTH 350 Graded ( system 2 ) UCESS 351 Graded ( system 2 ) NLARGE 352 Measured ( 0 to 999 ) NSMALL 353 Measured ( 0 to 999 ) AE 354 Character ( 50 ) AEREL 355 Graded ( system 17 )
User Diary Week 5	UD5 34	Not smoked cigarettes in past week Cigarettes per day Smoked products other than cigarettes Use smokeless tobacco/Nicotine/Smoking cessation products Number large (1g) Number small (0.5g) Adverse Event Adverse event related to snus	NOTSMK 358 Graded ( system 17 ) CIGDY 359 Real ( 0.00 to 999.00 ) SMKOTH 360 Graded ( system 2 ) UCESS 361 Graded ( system 2 ) NLARGE 362 Measured ( 0 to 999 ) NSMALL 363 Measured ( 0 to 999 ) AE 364 Character ( 50 ) AEREL 365 Graded ( system 17 )
Status review Week 1	SR1 35	Was status reviewed Was use of study product reviewed Number of cigarettes in week	SR2 378 Graded ( system 2 ) SR3 379 Graded ( system 2 ) SR10 380 Measured ( 0 to 999 )
Status review Week 2	SR2 36	Was status reviewed Was use of study product reviewed Number of cigarettes in week	SR2 383 Graded ( system 2 ) SR3 384 Graded ( system 2 ) SR10 385 Measured ( 0 to 999 )
Status review Week 3	SR3 37	Was status reviewed Was use of study product reviewed Number of cigarettes in week	SR2 389 Graded ( system 2 ) SR3 390 Graded ( system 2 ) SR10 391 Measured ( 0 to 999 )
Status review Week 4	SR4 38	Was status reviewed Was use of study product reviewed Number of cigarettes in week	SR2 394 Graded ( system 2 ) SR3 395 Graded ( system 2 ) SR10 396 Measured ( 0 to 999 )
Status review Week 6	SR6 39	Was status reviewed Was subject compliant Number of cigarettes smoked that week	SR2 399 Graded ( system 2 ) SR4 400 Graded ( system 2 ) SR5 401 Measured ( 0 to 999 )
Status review week 8	SR8 40	Was status reviewed Was use of study product reviewed Was subject compliant Number of cigarettes smoked that week	SR2 404 Graded ( system 2 ) SR3 405 Graded ( system 2 ) SR4 406 Graded ( system 2 ) SR5 407 Measured ( 0 to 999 )

**CONFIDENTIAL**

**Appendix A**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")

on the Quit Rate among Cigarette Smokers who wish to stop smoking.

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(US)

Status review Week 10	SR10	41				
Was status reviewed	SR2	410	Graded	( system 2 )		
Was use of study product reviewed	SR3	411	Graded	( system 2 )		
Was subject compliant	SR4	412	Graded	( system 2 )		
Number of cigarettes smoked that week	SR5	413	Measured	( 0 to 999 )		
Status review Week 13	SR13	42				
Was status reviewed	SR2	416	Graded	( system 2 )		
Was use of study product reviewed	SR3	417	Graded	( system 2 )		
Was subject compliant	SR4	418	Graded	( system 2 )		
Number of cigarettes smoked that week	SR5	419	Measured	( 0 to 999 )		
Status review Week 16	SR16	43				
Was status reviewed	SR2	422	Graded	( system 2 )		
Was use of study product reviewed	SR3	423	Graded	( system 2 )		
Was subject compliant	SR4	424	Graded	( system 2 )		
Number of cigarettes smoked that week	SR5	425	Measured	( 0 to 999 )		
Status review Week 20	SR20	44				
Was status reviewed	SR2	428	Graded	( system 2 )		
Was subject compliant	SR4	429	Graded	( system 2 )		
Number of cigarettes smoked that week	SR5	430	Measured	( 0 to 999 )		
Status review week 24	SR24	45				
Was status reviewed	SR2	433	Graded	( system 2 )		
Was subject compliant	SR4	434	Graded	( system 2 )		
Number of cigarettes smoked that week	SR5	435	Measured	( 0 to 999 )		
Status review Week 28	SR28	46				
Was status reviewed	SR2	438	Graded	( system 2 )		
Was subject compliant	SR4	439	Graded	( system 2 )		
Number of cigarettes smoked that week	SR5	440	Measured	( 0 to 999 )		

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**Appendix A**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials  
(US)

The grading systems used are as follows

**Grading Level (character equivalent)**

**System**

2    1    (y)    Yes  
2    (n)    No

17    1    (1)    Yes  
2    (2)    No  
3    (3)    Don't Know  
4    (4)    I have not experienced an AE

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**Appendix A**

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(Serbia)

Card Name	Short Name	Position	Short Name	Number	Type
Field Name					
CARD1	CARD1 (Page 1)	1	STUDYI	5	Character ( 8 )
Study Identifier			USUBJI	6	Character ( 20 )
Unique Subject Identifier			SITEID	7	Character ( 5 )
Study Site Identifier			SUBJID	8	Character ( 4 )
Subject Identifier for the Study			TRTP	9	Character ( 50 )
Planned Treatment			TRTPN	10	Real ( 0.00 to 99.00 )
Planned Treatment Number			TRTA	11	Character ( 50 )
Actual Treatment			TRTAN	12	Real ( 0.00 to 99.00 )
Actual Treatment Number			TRTSTD	13	Real ( 0.00 to 18018.00 )
Date of First Exposure to Treatment			TRTEND	14	Real ( 0.00 to 18351.00 )
Date of Last Exposure to Treatment			AGE	15	Real ( 0.00 to 99.00 )
Age in AGEU			AGEU	16	Character ( 5 )
Age Units			BRTHDT	17	Character ( 20 )
Date/Time of Birth			DBRTH	18	Real ( -5894.00 to 10389.00 )
Date of Birth			SEXC	19	Character ( 1 )
Sex			SEXN	20	Real ( 0.00 to 99.00 )
Sex, Numeric			WEIGHT	21	Real ( 0.00 to 136.00 )
Weight at Baseline (kg)			HEIGHT	22	Real ( 0.00 to 203.00 )
Height (cm)			BMI	23	Real ( 0.00 to 99.00 )
BMI (kg/m2)			SAFFL	24	Character ( 1 )
Safety Population Flag			ITTFL	25	Character ( 1 )
Intent-to-Treat Population Flag			MITTFL	26	Character ( 1 )
Modified Intent-to-Treat Population			COMPST	27	Character ( 1 )
Completed Study			DSDTC	28	Character ( 20 )
Disposition Date			DSREAS	29	Character ( 200 )
Primary Reason for Discontinuation			DSROTH	30	Character ( 200 )
Primary Reason for Discontinuation Other			WDRN24	31	Character ( 1 )
Withdrawn before Week 24			WDRN48	32	Character ( 1 )
Withdrawn before Week 48			WK24VI	33	Character ( 1 )
Attended Week 24 Visit			RANDBL	34	Character ( 1 )
Randomized at Baseline					

**CONFIDENTIAL**

**Appendix A**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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(Serbia)

Extent of Smoking Reduction at Week 12	WK12RE	35	Real	( -25.00 to 99.00 )
Extent of Smoking Reduction at Week 24	WK24RE	36	Real	( -50.00 to 100.00 )
Extent of Smoking Reduction at Week 36	WK36RE	37	Real	( 0.00 to 100.00 )
Extent of Smoking Reduction at Week 48	WK48RE	38	Real	( 0.00 to 100.00 )
Week 12 Reduction Category	WK12SR	39	Character	( 20 )
Week 12 Reduction Category Numeric	WK12R	40	Real	( 0.00 to 99.00 )
Week 24 Reduction Category	WK24SR	41	Character	( 20 )
Week 24 Reduction Category Numeric	WK24R	42	Real	( 0.00 to 99.00 )
Week 36 Reduction Category	WK36SR	43	Character	( 20 )
Week 36 Reduction Category Numeric	WK36R	44	Real	( 0.00 to 99.00 )
Week 48 Reduction Category	WK48SR	45	Character	( 20 )
CARD2	CARD2 (Page 2)	2		
Week 48 Reduction Category Numeric Treatment Unblinded?	WK48R TRTUBL	46 47	Real Character	( 0.00 to 99.00 ) ( 1 )
Smoking History (at Baseline)	SMHIST	3		
Age started smoking (Years)	AGEST	49	Measured	( 0 to 999 )
Average Cigarettes per day (previous year)	CIGDAY	50	Measured	( 0 to 999 )
Total number of quit attempts	TQUITA	51	Measured	( 0 to 999 )
Intention to participate	INTPAR	52	Character	( 30 )
Ever used NRT	USENRT	53	Graded	( system 2 )
Ever used other pharmaceutical products	OTHERP	54	Graded	( system 2 )
Ever used other cessation products	OTHERC	55	Graded	( system 2 )

**CONFIDENTIAL**

**Appendix A**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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(Serbia)

Expired CO (ppm)	ECO	4				
ECO week 0	ECO_0	58	Measured	( 0 to 9999 )		
ECO week 2	ECO_2	59	Measured	( 0 to 9999 )		
ECO week 6	ECO_6	60	Measured	( 0 to 9999 )		
ECO week 12	ECO_12	61	Measured	( 0 to 9999 )		
ECO week 18	ECO_18	62	Measured	( 0 to 9999 )		
ECO week 24	ECO_24	63	Measured	( 0 to 9999 )		
ECO week 30	ECO_30	64	Measured	( 0 to 9999 )		
ECO week 36	ECO_36	65	Measured	( 0 to 9999 )		
ECO week 42	ECO_42	66	Measured	( 0 to 9999 )		
ECO week 48	ECO_48	67	Measured	( 0 to 9999 )		
Fagerstrom Dependency Baseline	FT_0	5				
How soon after waking first cigarette	FT1	70	Character	( 20 )		
Difficult to refrain in places smoking forbidden	FT2	71	Graded	( system 2 )		
Which cigarette most difficult to give up	FT3	72	Character	( 20 )		
How many cigarettes per day	ft4	78	Character	( 20 )		
Smoke more in first hours than rest of day	FT5	73	Graded	( system 2 )		
Smoke even when ill in bed most of day	FT6	74	Graded	( system 2 )		
Total score	FT7	75	Measured	( 0 to 99 )		
Stopped smoking in previous week	FT8	76	Graded	( system 2 )		
Fagerstrom Week 24	FT_24	6				
How soon after waking first cigarette	FT1	80	Character	( 20 )		
Difficult to refrain in places smoking forbidden	FT2	81	Graded	( system 2 )		
Which cigarette most difficult to give up	FT3	82	Character	( 20 )		
How many cigarettes per day	ft4	83	Character	( 20 )		
Smoke more in first hours than rest of day	FT5	97	Graded	( system 2 )		
Smoke even when ill in bed most of day	FT6	84	Graded	( system 2 )		
Total score	FT7	85	Measured	( 0 to 99 )		
Stopped smoking in previous week	FT8	86	Graded	( system 2 )		

**CONFIDENTIAL**

**Appendix A**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials  
(Serbia)

Fagerstrom Dependency Week 48	FT_48	7			
How soon after waking first cigarette	FT1	89	Character	( 20 )	
Difficult to refrain in places smoking forbidden	FT2	90	Graded	( system 2 )	
Which cigarette most difficult to give up	FT3	91	Character	( 20 )	
How many cigarettes per day	ft4	92	Character	( 20 )	
Smoke more in first hours than rest of day	FT5	98	Graded	( system 2 )	
Smoke even when ill in bed most of day	FT6	93	Graded	( system 2 )	
Total score	FT7	94	Measured	( 0 to 99 )	
Stopped smoking in previous week	FT8	95	Graded	( system 2 )	
Self Reported Smoking Week 1	SS_1	8			
Average number of cigarettes per day	CIGD	100	Measured	( 0 to 99 )	
Consumed number of Large (1g) packets of SNUS per day	SNUSL	101	Measured	( 0 to 999 )	
Consumed number of Small packets of snus per day	SNUSS	102	Measured	( 0 to 999 )	
Self Reported Smoking Week 2	SS_2	9			
Average number of cigarettes per day	CIGD	105	Measured	( 0 to 99 )	
Consumed number of Large (1g) packets of SNUS per day	SNUSL	106	Measured	( 0 to 999 )	
Consumed number of Small packets of snus per day	SNUSS	107	Measured	( 0 to 999 )	
Self Reported Smoking Week 3	SS_3	10			
Average number of cigarettes per day	CIGD	110	Measured	( 0 to 99 )	
Consumed number of Large (1g) packets of SNUS per day	SNUSL	111	Measured	( 0 to 999 )	
Consumed number of Small packets of snus per day	SNUSS	112	Measured	( 0 to 999 )	
Self Reported Smoking Week 4	SS_4	11			
Average number of cigarettes per day	CIGD	115	Measured	( 0 to 99 )	
Consumed number of Large (1g) packets of SNUS per day	SNUSL	116	Measured	( 0 to 999 )	
Consumed number of Small packets of snus per day	SNUSS	117	Measured	( 0 to 999 )	
Self Reported Smoking Week 5	SS_5	12			
Average number of cigarettes per day	CIGD	120	Measured	( 0 to 99 )	
Consumed number of Large (1g) packets of SNUS per day	SNUSL	121	Measured	( 0 to 999 )	
Consumed number of Small packets of snus per day	SNUSS	122	Measured	( 0 to 999 )	

**CONFIDENTIAL**

**Appendix A**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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(Serbia)

Self Reported Smoking Week 6	SS_6	13				
Average number of cigarettes per day	CIGD	125	Measured	( 0 to 99 )		
Consumed number of Large (1g) packets of SNUS per day	SNUSL	126	Measured	( 0 to 999 )		
Consumed number of Small packets of snus per day	SNUSS	127	Measured	( 0 to 999 )		
Self Reported Smoking Week 7	SS_7	14				
Average number of cigarettes per day	CIGD	130	Measured	( 0 to 99 )		
Consumed number of Large (1g) packets of SNUS per day	SNUSL	131	Measured	( 0 to 999 )		
Consumed number of Small packets of snus per day	SNUSS	132	Measured	( 0 to 999 )		
Self Reported Smoking Week 8	SS_8	15				
Average number of cigarettes per day	CIGD	135	Measured	( 0 to 99 )		
Consumed number of Large (1g) packets of SNUS per day	SNUSL	136	Measured	( 0 to 999 )		
Consumed number of Small packets of snus per day	SNUSS	137	Measured	( 0 to 999 )		
Self Reported Smoking Week 9	SS_9	16				
Average number of cigarettes per day	CIGD	140	Measured	( 0 to 99 )		
Consumed number of Large (1g) packets of SNUS per day	SNUSL	141	Measured	( 0 to 999 )		
Consumed number of Small packets of snus per day	SNUSS	142	Measured	( 0 to 999 )		
Self Reported Smoking Week 10	SS_10	17				
Average number of cigarettes per day	CIGD	145	Measured	( 0 to 99 )		
Consumed number of Large (1g) packets of SNUS per day	SNUSL	146	Measured	( 0 to 999 )		
Consumed number of Small packets of snus per day	SNUSS	147	Measured	( 0 to 999 )		
Self Reported Smoking Week 11	SS_11	18				
Average number of cigarettes per day	CIGD	150	Measured	( 0 to 99 )		
Consumed number of Large (1g) packets of SNUS per day	SNUSL	151	Measured	( 0 to 999 )		
Consumed number of Small packets of snus per day	SNUSS	152	Measured	( 0 to 999 )		
Self Reported Smoking Week 12	SS_12	19				
Average number of cigarettes per day	CIGD	155	Measured	( 0 to 99 )		
Consumed number of Large (1g) packets of SNUS per day	SNUSL	156	Measured	( 0 to 999 )		
Consumed number of Small packets of snus per day	SNUSS	157	Measured	( 0 to 999 )		

**CONFIDENTIAL**

**Appendix A**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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(Serbia)

Self Reported Smoking Week 13	SS_13	20				
	Average number of cigarettes per day		CIGD	160	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	161	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	162	Measured	( 0 to 999 )
Self Reported Smoking Week 14	SS_14	21				
	Average number of cigarettes per day		CIGD	165	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	166	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	167	Measured	( 0 to 999 )
Self Reported Smoking Week 15	SS_15	22				
	Average number of cigarettes per day		CIGD	170	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	171	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	172	Measured	( 0 to 999 )
Self Reported Smoking Week 16	SS_16	23				
	Average number of cigarettes per day		CIGD	175	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	176	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	177	Measured	( 0 to 999 )
Self Reported Smoking Week 17	SS_17	24				
	Average number of cigarettes per day		CIGD	180	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	181	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	182	Measured	( 0 to 999 )
Self Reported Smoking Week 18	SS_18	25				
	Average number of cigarettes per day		CIGD	185	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	186	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	187	Measured	( 0 to 999 )
Self Reported Smoking Week 19	SS_19	26				
	Average number of cigarettes per day		CIGD	190	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	191	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	192	Measured	( 0 to 999 )

**CONFIDENTIAL**

**Appendix A**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials  
(Serbia)

Self Reported Smoking Week 20	SS_20	27				
	Average number of cigarettes per day		CIGD	195	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	196	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	197	Measured	( 0 to 999 )
Self Reported Smoking Week 21	SS_21	28				
	Average number of cigarettes per day		CIGD	200	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	201	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	202	Measured	( 0 to 999 )
Self Reported Smoking Week 22	SS_22	29				
	Average number of cigarettes per day		CIGD	205	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	206	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	207	Measured	( 0 to 999 )
Self Reported Smoking Week 23	SS_23	30				
	Average number of cigarettes per day		CIGD	210	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	211	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	212	Measured	( 0 to 999 )
Self Reported Smoking Week 24	SS_24	31				
	Average number of cigarettes per day		CIGD	215	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	216	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	217	Measured	( 0 to 999 )
Self Reported Smoking Week 25	SS_25	32				
	Average number of cigarettes per day		CIGD	220	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	221	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	222	Measured	( 0 to 999 )
Self Reported Smoking Week 26	SS_26	33				
	Average number of cigarettes per day		CIGD	225	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	226	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	227	Measured	( 0 to 999 )

**CONFIDENTIAL**

**Appendix A**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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(Serbia)

Self Reported Smoking Week 27	SS_27	34				
	Average number of cigarettes per day		CIGD	230	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	231	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	232	Measured	( 0 to 999 )
Self Reported Smoking Week 28	SS_28	35				
	Average number of cigarettes per day		CIGD	235	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	236	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	237	Measured	( 0 to 999 )
Self Reported Smoking Week 29	SS_29	36				
	Average number of cigarettes per day		CIGD	240	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	241	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	242	Measured	( 0 to 999 )
Self Reported Smoking Week 30	SS_30	37				
	Average number of cigarettes per day		CIGD	245	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	246	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	247	Measured	( 0 to 999 )
Self Reported Smoking Week 31	SS_31	38				
	Average number of cigarettes per day		CIGD	250	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	251	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	252	Measured	( 0 to 999 )
Self Reported Smoking Week 32	SS_32	39				
	Average number of cigarettes per day		CIGD	255	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	256	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	257	Measured	( 0 to 999 )
Self Reported Smoking Week 33	SS_33	40				
	Average number of cigarettes per day		CIGD	260	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	261	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	262	Measured	( 0 to 999 )

**CONFIDENTIAL**

**Appendix A**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

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(Serbia)

Self Reported Smoking Week 34	SS_34	41				
	Average number of cigarettes per day		CIGD	265	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	266	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	267	Measured	( 0 to 999 )
Self Reported Smoking Week 35	SS_35	42				
	Average number of cigarettes per day		CIGD	270	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	271	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	272	Measured	( 0 to 999 )
Self Reported Smoking Week 36	SS_36	43				
	Average number of cigarettes per day		CIGD	275	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	276	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	277	Measured	( 0 to 999 )
Self Reported Smoking Week 37	SS_37	44				
	Average number of cigarettes per day		CIGD	280	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	281	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	282	Measured	( 0 to 999 )
Self Reported Smoking Week 38	SS_38	45				
	Average number of cigarettes per day		CIGD	285	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	286	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	287	Measured	( 0 to 999 )
Self Reported Smoking Week 39	SS_39	46				
	Average number of cigarettes per day		CIGD	290	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	291	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	292	Measured	( 0 to 999 )
Self Reported Smoking Week 40	SS_40	47				
	Average number of cigarettes per day		CIGD	295	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	296	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	297	Measured	( 0 to 999 )

**CONFIDENTIAL**

**Appendix A**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials  
(Serbia)

Self Reported Smoking Week 41	SS_41	48				
Average number of cigarettes per day	CIGD	300	Measured	( 0 to 99 )		
Consumed number of Large (1g) packets of SNUS per day	SNUSL	301	Measured	( 0 to 999 )		
Consumed number of Small packets of snus per day	SNUSS	302	Measured	( 0 to 999 )		
Self Reported Smoking Week 42	SS_42	49				
Average number of cigarettes per day	CIGD	305	Measured	( 0 to 99 )		
Consumed number of Large (1g) packets of SNUS per day	SNUSL	306	Measured	( 0 to 999 )		
Consumed number of Small packets of snus per day	SNUSS	307	Measured	( 0 to 999 )		
Self Reported Smoking Week 43	SS_43	50				
Average number of cigarettes per day	CIGD	310	Measured	( 0 to 99 )		
Consumed number of Large (1g) packets of SNUS per day	SNUSL	311	Measured	( 0 to 999 )		
Consumed number of Small packets of snus per day	SNUSS	312	Measured	( 0 to 999 )		
Self Reported Smoking Week 44	SS_44	51				
Average number of cigarettes per day	CIGD	315	Measured	( 0 to 99 )		
Consumed number of Large (1g) packets of SNUS per day	SNUSL	316	Measured	( 0 to 999 )		
Consumed number of Small packets of snus per day	SNUSS	317	Measured	( 0 to 999 )		
Self Reported Smoking Week 45	SS_45	52				
Average number of cigarettes per day	CIGD	320	Measured	( 0 to 99 )		
Consumed number of Large (1g) packets of SNUS per day	SNUSL	321	Measured	( 0 to 999 )		
Consumed number of Small packets of snus per day	SNUSS	322	Measured	( 0 to 999 )		
Self Reported Smoking Week 46	SS_46	53				
Average number of cigarettes per day	CIGD	325	Measured	( 0 to 99 )		
Consumed number of Large (1g) packets of SNUS per day	SNUSL	326	Measured	( 0 to 999 )		
Consumed number of Small packets of snus per day	SNUSS	327	Measured	( 0 to 999 )		
Self Reported Smoking Week 47	SS_47	54				
Average number of cigarettes per day	CIGD	330	Measured	( 0 to 99 )		
Consumed number of Large (1g) packets of SNUS per day	SNUSL	331	Measured	( 0 to 999 )		
Consumed number of Small packets of snus per day	SNUSS	332	Measured	( 0 to 999 )		

**CONFIDENTIAL**

**Appendix A**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials  
(Serbia)

Self Reported Smoking Week 48	SS_48	55				
	Average number of cigarettes per day		CIGD	335	Measured	( 0 to 99 )
	Consumed number of Large (1g) packets of SNUS per day		SNUSL	336	Measured	( 0 to 999 )
	Consumed number of Small packets of snus per day		SNUSS	337	Measured	( 0 to 999 )
Efficacy Results Week 12	EFF12	56				
	Reduced smoking by 50%		REDSMK	341	Graded	( system 2 )
	Stopped smoking in previous week		STOP1	343	Graded	( system 2 )
	Stopped smoking in previous 4 weeks		STOP4	344	Graded	( system 2 )
Efficacy Assess Week 24	EFF24	57				
	Reduced smoking by 50%		REDSMK	347	Graded	( system 2 )
	Stopped smoking in previous week		STOP1	348	Graded	( system 2 )
	Stopped smoking in previous 4 weeks		STOP4	349	Graded	( system 2 )
Efficacy Asses Week 36	EFF36	58				
	Reduced smoking by 50%		REDSMK	352	Graded	( system 2 )
	Stopped smoking in previous week		STOP1	353	Graded	( system 2 )
	Stopped smoking in previous 4 weeks		STOP4	354	Graded	( system 2 )
	Stopped smoking in previous 12 weeks		STOP12	361	Graded	( system 2 )
	Stopped smoking in previous 24 weeks		STOP24	363	Graded	( system 2 )
Efficacy Asses Week 48	EFF48	59				
	Reduced smoking by 50%		REDSMK	357	Graded	( system 2 )
	Stopped smoking in previous week		STOP1	358	Graded	( system 2 )
	Stopped smoking in previous 4 weeks		STOP4	359	Graded	( system 2 )
	Stopped smoking in previous 12 weeks		STOP12	362	Graded	( system 2 )
	Stopped smoking in previous 24 weeks		STOP24	364	Graded	( system 2 )

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**Appendix A**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials  
(Serbia)

Outcomes	OUTCO M	60			
Primary Outcome: smoking cessation 6-28 (US) 25-48 (Serbia)			P_OUT	366	Graded ( system 2 )
Smoke-free week 6 (US) week 24 (Serbia)	S_OUT1	368	Graded	( system 2 )	
Smoke-free week 16 (US) week 36 (Serbia)	S_OUT2	369	Graded	( system 2 )	
Smoke-free week 28 (US) week 48 (Serbia)	S_OUT3	370	Graded	( system 2 )	
Smoke-free weeks 25-28 (US) 45-48 (Serbia)	S_OUT4	396	Graded	( system 2 )	
Smoke-free weeks 17-28 (US) 37-48 (Serbia)	S_OUT5	397	Graded	( system 2 )	
Compliance	COMP	61			
Tried the study products at least once every day (Week 1)	TRY_1	375	Graded	( system 2 )	
Used source of nicotine other than cigs or snus (Week 1)	UOTH1	376	Graded	( system 2 )	
Tried the study products at least once every day (Week 2)	TRY_2	377	Graded	( system 2 )	
Used source of nicotine other than cigs or snus (Week 2)	UOTH2	378	Graded	( system 2 )	
Tried the study products at least once every day (Week 6)	TRY_6	379	Graded	( system 2 )	
Used source of nicotine other than cigs or snus (Week 6)	UOTH6	380	Graded	( system 2 )	
Tried the study products at least once every day (Week 9)	TRY_9	381	Graded	( system 2 )	
Used source of nicotine other than cigs or snus (Week 9)	UOTH9	382	Graded	( system 2 )	
Tried the study products at least once every day (Week 12)	TRY_12	383	Graded	( system 2 )	
Used source of nicotine other than cigs or snus (Week 12)	UOTH12	384	Graded	( system 2 )	
Tried the study products at least once every day (Week 18)	TRY_18	385	Graded	( system 2 )	
Used source of nicotine other than cigs or snus (Week 18)	UOTH18	386	Graded	( system 2 )	
Tried the study products at least once every day (Week 24)	TRY_24	387	Graded	( system 2 )	
Used source of nicotine other than cigs or snus (Week 24)	UOTH24	388	Graded	( system 2 )	
Tried the study products at least once every day (Week 30)	TRY_30	389	Graded	( system 2 )	
Used source of nicotine other than cigs or snus (Week 30)	UOTH30	390	Graded	( system 2 )	
Tried the study products at least once every day (Week 36)	TRY_36	391	Graded	( system 2 )	
Used source of nicotine other than cigs or snus (Week 36)	UOTH36	392	Graded	( system 2 )	
Tried the study products at least once every day (Week 48)	TRY_48	393	Graded	( system 2 )	
Used source of nicotine other than cigs or snus (Week 48)	UOTH48	394	Graded	( system 2 )	

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**Appendix A**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")

on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

(Serbia)

The grading systems used are as follows

**Grading Level (character equivalent)**

**System**

2	1	(y)	Yes
2	(n)		No

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**APPENDIX B**

**Listing of individual subject data used in the analysis**

The data are shown, in subject ID order, and within study in sections as follows:

<b><u>Listing</u></b>	<b><u>Contents</u></b>
1	Demographics, Smoking History, Fagerström dependency test (Baseline)
2	Previous use of NRT, Other Pharmaceuticals, Other cessation aids and Quit Attempts
3	Expired Air CO (ppm)
4	User Diary : subject not smoked cigarettes in past week*
5	Self Reported Smoking : Average number of Cigarettes per day (Serbia)
6	User Diary : Average number of Cigarettes per day (US)
7	User Diary : Smoked Tobacco Products other than Cigarettes (US)*
8	Efficacy Assessments: Reduced or Stopped Smoking (Serbia)
9	Dates of Treatments and Completion/Withdrawal
10	Outcome

\* Data only available for US

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**Listing 1: Demographics, Smoking History, Fagerström Dependency Test (Baseline)**  
Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

**(Serbia)**

Subject ID	Study Identifier	Study Site ID	Sex	Age (Years)	Age Start Smoking	Average Cigarettes per day (previous year)	Fagerström Dependency Test
1001	SM 07-01	01	m	60.00	18	50	10
1002	SM 07-01	01	m	58.00	13	30	6
1003	SM 07-01	01	f	35.00	14	25	7
1004	SM 07-01	01	f	56.00	19	20	7
1005	SM 07-01	01	f	55.00	22	30	7
1006	SM 07-01	01	f	58.00	20	25	7
1007	SM 07-01	01	m	55.00	20	20	5
1008	SM 07-01	01	m	40.00	12	60	10
1009	SM 07-01	01	f	50.00	20	30	9
1010	SM 07-01	01	m	55.00	18	30	7
1011	SM 07-01	01	f	43.00	16	60	10
1012	SM 07-01	01	m	56.00	19	40	9
1013	SM 07-01	01	f	42.00	18	30	7
1014	SM 07-01	01	f	33.00	16	40	8
1015	SM 07-01	01	m	23.00	14	30	8
1016	SM 07-01	01	m	53.00	32	40	10
1017	SM 07-01	01	m	56.00	23	30	6
1018	SM 07-01	01	m	49.00	20	30	7
1019	SM 07-01	01	m	40.00	18	25	9
1020	SM 07-01	01	m	47.00	21	30	8
1021	SM 07-01	01	m	44.00	20	20	5
1022	SM 07-01	01	f	46.00	17	20	6
1023	SM 07-01	01	m	44.00	17	35	7
1024	SM 07-01	01	m	53.00	19	30	5
1025	SM 07-01	01	f	57.00	33	20	5
1026	SM 07-01	01	m	60.00	17	40	9
1027	SM 07-01	01	f	51.00	20	20	7
1028	SM 07-01	01	f	56.00	20	20	4
1029	SM 07-01	01	m	49.00	18	40	8
1030	SM 07-01	01	f	44.00	21	20	6
1031	SM 07-01	01	m	36.00	19	30	7
1032	SM 07-01	01	m	46.00	20	25	7
1033	SM 07-01	01	f	39.00	20	25	7
1034	SM 07-01	01	m	28.00	16	30	6
1035	SM 07-01	01	m	45.00	15	15	2
1036	SM 07-01	01	f	43.00	15	20	4
1037	SM 07-01	01	f	57.00	35	20	4
1038	SM 07-01	01	m	46.00	16	30	7
1039	SM 07-01	01	m	33.00	18	25	9
1040	SM 07-01	01	m	49.00	22	30	5
1041	SM 07-01	01	m	33.00	18	25	7
1042	SM 07-01	01	m	29.00	18	30	6
1043	SM 07-01	01	m	31.00	15	20	3
1044	SM 07-01	01	m	55.00	12	40	10
1045	SM 07-01	01	m	46.00	18	20	3
1046	SM 07-01	01	m	32.00	15	20	6
1047	SM 07-01	01	m	35.00	16	30	9
1048	SM 07-01	01	m	38.00	20	40	8
1049	SM 07-01	01	m	39.00	23	40	8
1050	SM 07-01	01	m	44.00	16	35	10
1205	SM 07-01	01	f	58.00	30	30	9

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**Listing 1: Demographics, Smoking History, Fagerström Dependency Test (Baseline)**  
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A meta-analysis of results from two randomized clinical trials

**(Serbia)**

Subject ID	Study Identifier	Study Site ID	Sex	Age (Years)	Age Start Smoking	Average Cigarettes per day (previous year)	Fagerström Dependency Test
1206	SM 07-01	01	m	47.00	15	50	10
1207	SM 07-01	01	m	47.00	18	30	8
1208	SM 07-01	01	f	36.00	17	30	6
1209	SM 07-01	01	f	57.00	53	15	3
1210	SM 07-01	01	f	46.00	18	25	8
1211	SM 07-01	01	f	40.00	16	30	6
1212	SM 07-01	01	m	46.00	18	20	7
1213	SM 07-01	01	m	29.00	17	30	8
1214	SM 07-01	01	m	55.00	17	40	7
1215	SM 07-01	01	f	53.00	20	20	6
1216	SM 07-01	01	f	55.00	18	20	7
1217	SM 07-01	01	f	52.00	37	30	7
1218	SM 07-01	01	f	23.00	14	30	8
1219	SM 07-01	01	m	35.00	16	30	8
1220	SM 07-01	01	f	40.00	18	25	7
1221	SM 07-01	01	m	55.00	18	30	7
1222	SM 07-01	01	f	35.00	20	30	9
1223	SM 07-01	01	m	41.00	20	25	4
1224	SM 07-01	01	m	42.00	23	35	9
1225	SM 07-01	01	m	45.00	18	40	7
1226	SM 07-01	01	m	27.00	15	25	6
1227	SM 07-01	01	f	51.00	17	25	8
1228	SM 07-01	01	f	44.00	20	20	4
1229	SM 07-01	01	f	50.00	30	20	7
1230	SM 07-01	01	m	58.00	15	20	5
1231	SM 07-01	01	f	27.00	16	20	7
1232	SM 07-01	01	f	27.00	16	20	3
1233	SM 07-01	01	f	53.00	34	20	5
1234	SM 07-01	01	m	49.00	20	40	6
1235	SM 07-01	01	f	55.00	26	20	5
1236	SM 07-01	01	f	32.00	14	30	6
1237	SM 07-01	01	f	62.00	21	30	8
1238	SM 07-01	01	f	44.00	33	15	5
1239	SM 07-01	01	m	31.00	17	25	8
1240	SM 07-01	01	f	33.00	17	20	6
1241	SM 07-01	01	m	53.00	24	20	7
1242	SM 07-01	01	f	51.00	20	20	6
1243	SM 07-01	01	f	42.00	18	20	5
1244	SM 07-01	01	f	38.00	17	40	9
1245	SM 07-01	01	f	38.00	21	20	8
1246	SM 07-01	01	m	38.00	17	60	9
1247	SM 07-01	01	m	37.00	19	30	9
1325	SM 07-01	02	m	45.00	15	10	5
1326	SM 07-01	02	m	21.00	16	20	6
1327	SM 07-01	02	m	20.00	14	30	6
1328	SM 07-01	02	f	25.00	19	30	7
1329	SM 07-01	02	m	27.00	20	20	5
1330	SM 07-01	02	m	24.00	15	20	3
1331	SM 07-01	02	f	23.00	20	20	3
1332	SM 07-01	02	f	27.00	14	30	6
1333	SM 07-01	02	f	42.00	17	20	4

**CONFIDENTIAL**

**Listing 1: Demographics, Smoking History, Fagerström Dependency Test (Baseline)**  
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A meta-analysis of results from two randomized clinical trials

**(Serbia)**

Subject ID	Study Identifier	Study Site ID	Sex	Age (Years)	Age Start Smoking	Average Cigarettes per day (previous year)	Fagerström Dependency Test
1334	SM 07-01	02	m	50.00	14	40	7
1335	SM 07-01	02	m	38.00	19	30	6
1336	SM 07-01	02	f	33.00	18	20	4
1337	SM 07-01	02	f	39.00	24	20	3
1338	SM 07-01	02	f	54.00	16	25	8
1339	SM 07-01	02	f	45.00	24	25	7
1340	SM 07-01	02	m	54.00	20	40	10
1341	SM 07-01	02	f	57.00	18	25	8
1342	SM 07-01	02	f	33.00	15	20	5
1343	SM 07-01	02	f	32.00	16	20	5
1344	SM 07-01	02	f	54.00	15	20	3
1345	SM 07-01	02	f	24.00	18	15	4
1346	SM 07-01	02	m	49.00	18	20	6
1347	SM 07-01	02	m	42.00	20	20	4
1348	SM 07-01	02	m	37.00	19	20	4
1349	SM 07-01	02	m	30.00	20	30	6
2001	SM 07-01	02	f	49.00	20	20	8
2002	SM 07-01	02	f	36.00	19	40	10
2003	SM 07-01	02	f	28.00	15	20	8
2004	SM 07-01	02	m	47.00	18	40	6
2005	SM 07-01	02	f	37.00	18	20	4
2006	SM 07-01	02	f	36.00	15	20	5
2007	SM 07-01	02	m	49.00	17	20	8
2008	SM 07-01	02	m	45.00	18	20	8
2009	SM 07-01	02	f	55.00	12	20	5
2010	SM 07-01	02	f	52.00	17	40	6
2011	SM 07-01	02	f	57.00	20	20	3
2012	SM 07-01	02	f	47.00	18	30	7
2013	SM 07-01	02	f	51.00	18	40	8
2014	SM 07-01	02	f	32.00	22	15	3
2015	SM 07-01	02	m	32.00	18	25	7
2016	SM 07-01	02	f	38.00	16	30	8
2017	SM 07-01	02	f	50.00	22	20	4
2018	SM 07-01	02	f	49.00	21	20	3
2019	SM 07-01	02	f	49.00	19	40	7
2020	SM 07-01	02	f	41.00	26	20	5
2021	SM 07-01	02	f	34.00	16	30	7
2022	SM 07-01	02	m	51.00	15	40	9
2023	SM 07-01	02	f	52.00	15	40	7
2024	SM 07-01	02	f	41.00	19	30	6
2025	SM 07-01	02	f	43.00	20	20	4
2026	SM 07-01	02	f	29.00	21	15	2
2027	SM 07-01	02	f	30.00	19	10	3
2028	SM 07-01	02	f	64.00	18	30	8
2029	SM 07-01	02	f	41.00	18	30	8
2030	SM 07-01	02	f	55.00	19	30	8
2031	SM 07-01	02	m	23.00	19	15	2
2032	SM 07-01	02	m	47.00	20	30	8
2033	SM 07-01	02	m	50.00	18	20	6
2034	SM 07-01	02	f	60.00	35	20	2
2035	SM 07-01	02	m	52.00	18	60	9

**CONFIDENTIAL**

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**(Serbia)**

Subject ID	Study Identifier	Study Site ID	Sex	Age (Years)	Age Start Smoking	Average Cigarettes per day (previous year)	Fagerström Dependency Test
2036	SM 07-01	02	m	56.00	16	25	4
2037	SM 07-01	02	m	51.00	18	25	7
2038	SM 07-01	02	f	45.00	17	25	8
2039	SM 07-01	02	f	47.00	15	20	4
2040	SM 07-01	02	f	40.00	17	20	4
2041	SM 07-01	02	f	21.00	16	25	8
2042	SM 07-01	02	f	48.00	20	20	6
2043	SM 07-01	02	f	53.00	27	20	5
2044	SM 07-01	02	f	30.00	20	30	8
2045	SM 07-01	02	f	52.00	17	30	6
2046	SM 07-01	02	f	52.00	17	20	6
2047	SM 07-01	02	f	23.00	17	20	6
2048	SM 07-01	02	m	47.00	18	30	9
2049	SM 07-01	02	f	37.00	20	20	2
2050	SM 07-01	02	f	49.00	18	20	5
2205	SM 07-01	02	m	24.00	15	30	5
2206	SM 07-01	02	f	60.00	30	20	6
2207	SM 07-01	02	f	27.00	17	25	3
2208	SM 07-01	02	m	39.00	16	25	5
2209	SM 07-01	02	f	56.00	25	20	4
2210	SM 07-01	02	f	35.00	18	15	1
2211	SM 07-01	02	m	41.00	18	40	10
2212	SM 07-01	02	f	41.00	18	30	8
2213	SM 07-01	02	f	31.00	19	25	5
2214	SM 07-01	02	f	28.00	18	25	6
2215	SM 07-01	02	m	48.00	15	30	6
2216	SM 07-01	02	m	52.00	19	40	6
2217	SM 07-01	02	f	28.00	20	30	5
2218	SM 07-01	02	f	54.00	15	20	4
2219	SM 07-01	02	f	45.00	25	20	5
2220	SM 07-01	02	m	52.00	22	25	7
2221	SM 07-01	02	f	51.00	15	25	6
2222	SM 07-01	02	f	41.00	33	15	3
2223	SM 07-01	02	f	31.00	17	10	2
2224	SM 07-01	02	f	55.00	19	25	6
2225	SM 07-01	02	f	54.00	18	20	6
2226	SM 07-01	02	m	43.00	19	40	10
2227	SM 07-01	02	m	35.00	18	20	5
2228	SM 07-01	02	f	41.00	17	20	3
2229	SM 07-01	02	f	51.00	17	25	6
2230	SM 07-01	02	f	56.00	25	20	4
2231	SM 07-01	02	f	60.00	18	15	4
2232	SM 07-01	02	f	51.00	18	20	7
2233	SM 07-01	02	f	51.00	17	40	7
2234	SM 07-01	02	m	54.00	15	60	7
2235	SM 07-01	02	m	47.00	16	30	7
2236	SM 07-01	02	m	27.00	17	15	2
2237	SM 07-01	02	f	29.00	15	20	5
2238	SM 07-01	02	f	51.00	20	10	5
2239	SM 07-01	02	f	52.00	18	30	6
2240	SM 07-01	02	f	29.00	16	20	6

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**(Serbia)**

Subject ID	Study Identifier	Study Site ID	Sex	Age (Years)	Age Start Smoking	Average Cigarettes per day (previous year)	Fagerström Dependency Test
2241	SM 07-01	02	m	27.00	15	30	7
2242	SM 07-01	02	f	55.00	17	40	6
2243	SM 07-01	02	f	42.00	15	20	6
2244	SM 07-01	02	f	29.00	17	20	6
2245	SM 07-01	02	f	46.00	18	15	2
2246	SM 07-01	02	f	39.00	23	20	4
2247	SM 07-01	02	m	53.00	47	15	1
2248	SM 07-01	02	f	45.00	20	20	5
2249	SM 07-01	02	f	59.00	20	30	5
2250	SM 07-01	02	f	53.00	16	10	6
2251	SM 07-01	02	f	52.00	20	20	6
2252	SM 07-01	02	f	51.00	18	30	6
2253	SM 07-01	02	m	45.00	15	20	6
2254	SM 07-01	02	m	55.00	17	40	8
2255	SM 07-01	02	f	33.00	17	25	3
2256	SM 07-01	02	f	30.00	19	20	1
2257	SM 07-01	02	m	57.00	27	30	10
2258	SM 07-01	02	f	49.00	20	20	7
2259	SM 07-01	02	m	28.00	18	20	7
2260	SM 07-01	02	f	43.00	20	25	7
2261	SM 07-01	02	f	39.00	18	20	6
2262	SM 07-01	02	f	52.00	19	15	5
2263	SM 07-01	02	f	41.00	25	40	10
2264	SM 07-01	02	f	56.00	21	15	8
2265	SM 07-01	02	f	43.00	15	50	10
2266	SM 07-01	02	f	48.00	16	20	4
2267	SM 07-01	02	f	41.00	17	40	10
2268	SM 07-01	02	f	42.00	20	20	7
2269	SM 07-01	02	m	37.00	17	20	3
2270	SM 07-01	02	f	60.00	22	15	3
2271	SM 07-01	02	f	46.00	22	25	6
2272	SM 07-01	02	f	54.00	17	35	9
2273	SM 07-01	02	f	55.00	20	35	8
2274	SM 07-01	02	f	45.00	21	15	5
2275	SM 07-01	02	f	52.00	19	20	8
2276	SM 07-01	02	f	51.00	23	30	7
2277	SM 07-01	02	f	50.00	20	15	2
2278	SM 07-01	02	m	40.00	18	30	6
2279	SM 07-01	02	m	39.00	14	60	9
2280	SM 07-01	02	f	33.00	22	15	2
2281	SM 07-01	02	m	33.00	18	20	7
2282	SM 07-01	02	f	41.00	23	30	9
2283	SM 07-01	02	f	49.00	23	40	8
2284	SM 07-01	02	m	32.00	18	30	8
2285	SM 07-01	02	f	47.00	19	15	4
2286	SM 07-01	02	f	29.00	17	20	6
2287	SM 07-01	02	m	51.00	20	15	4
2288	SM 07-01	02	m	30.00	19	20	4
2289	SM 07-01	02	m	39.00	16	60	8
2290	SM 07-01	02	m	36.00	17	20	8
2291	SM 07-01	02	m	29.00	15	40	6

**CONFIDENTIAL**

**Listing 1: Demographics, Smoking History, Fagerström Dependency Test (Baseline)**  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

**(Serbia)**

Subject ID	Study Identifier	Study Site ID	Sex	Age (Years)	Age Start Smoking	Average Cigarettes per day (previous year)	Fagerström Dependency Test
2292	SM 07-01	02	f	31.00	18	20	8
2293	SM 07-01	02	m	28.00	19	20	3
2294	SM 07-01	02	m	47.00	17	40	7
2295	SM 07-01	02	m	43.00	19	40	8
2296	SM 07-01	02	f	26.00	14	20	6
2297	SM 07-01	02	f	28.00	21	20	5
2298	SM 07-01	02	m	29.00	17	25	5
2299	SM 07-01	02	f	43.00	18	40	6
2300	SM 07-01	02	m	44.00	22	25	3
2301	SM 07-01	02	m	55.00	20	30	5
2302	SM 07-01	02	m	24.00	16	20	3
2303	SM 07-01	02	f	49.00	21	20	5
2304	SM 07-01	02	m	49.00	23	25	6
2305	SM 07-01	02	f	56.00	25	20	5
2306	SM 07-01	02	f	52.00	15	40	8
3001	SM 07-01	02	m	52.00	24	20	6
3002	SM 07-01	02	f	37.00	13	20	6
3003	SM 07-01	02	f	38.00	24	30	5
3004	SM 07-01	02	m	50.00	20	50	9
3006	SM 07-01	02	f	45.00	22	20	3
3007	SM 07-01	02	f	48.00	20	20	1
3008	SM 07-01	02	f	50.00	23	20	5
3009	SM 07-01	02	f	48.00	18	40	8
3010	SM 07-01	02	f	38.00	15	20	6
3011	SM 07-01	02	m	45.00	30	15	3
3012	SM 07-01	02	f	54.00	14	30	8
3013	SM 07-01	02	m	51.00	19	30	8
3014	SM 07-01	02	f	50.00	18	25	8
3015	SM 07-01	02	m	34.00	17	50	9
3016	SM 07-01	02	f	43.00	17	20	4
3017	SM 07-01	02	f	45.00	17	20	7
3018	SM 07-01	02	m	34.00	19	35	8
3019	SM 07-01	02	f	35.00	19	25	6
3020	SM 07-01	02	m	55.00	27	35	7
3021	SM 07-01	02	f	48.00	20	30	8
3022	SM 07-01	02	f	33.00	15	30	7
3023	SM 07-01	02	f	56.00	20	20	5
3024	SM 07-01	02	f	39.00	16	40	7
3025	SM 07-01	02	f	53.00	18	30	9
3026	SM 07-01	02	f	48.00	15	25	7
3027	SM 07-01	02	m	48.00	14	30	8
3028	SM 07-01	02	m	50.00	15	40	8
3029	SM 07-01	02	f	37.00	15	30	7
3030	SM 07-01	02	m	44.00	20	40	7
3031	SM 07-01	02	f	53.00	10	20	8
3032	SM 07-01	02	f	43.00	17	60	9
3033	SM 07-01	02	f	57.00	15	20	5
3034	SM 07-01	02	f	57.00	17	20	7
3035	SM 07-01	02	m	61.00	20	30	7
3036	SM 07-01	02	f	60.00	28	25	9
3037	SM 07-01	02	f	32.00	18	15	7

**CONFIDENTIAL**

**Listing 1: Demographics, Smoking History, Fagerström Dependency Test (Baseline)**  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

**(Serbia)**

Subject ID	Study Identifier	Study Site ID	Sex	Age (Years)	Age Start Smoking	Average Cigarettes per day (previous year)	Fagerström Dependency Test
3038	SM 07-01	02	f	38.00	19	20	4
3039	SM 07-01	02	f	26.00	18	15	1
3040	SM 07-01	02	f	46.00	17	40	9
3041	SM 07-01	02	f	40.00	13	30	7
3042	SM 07-01	02	f	58.00	18	30	8
3043	SM 07-01	02	f	54.00	27	15	2
3044	SM 07-01	02	f	46.00	20	15	3
3045	SM 07-01	02	f	50.00	20	20	6
3046	SM 07-01	02	m	44.00	15	40	7
3047	SM 07-01	02	f	43.00	20	20	5
3048	SM 07-01	02	m	45.00	13	15	1
3049	SM 07-01	02	f	27.00	18	25	6
3050	SM 07-01	02	f	52.00	19	25	8

**CONFIDENTIAL**

**Listing 1: Demographics, Smoking History, Fagerström Dependency Test (Baseline)**  
Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

(USA)

Subject ID	Study Identifier	Study Site ID	Sex	Age (Years)	Age Start Smoking	Average Cigarettes per day (previous year)	Fagerström Dependency Test
R1001	SM08-01	CDB_001	f	64.00	26	15	5
R1002	SM08-01	CDB_001	f	57.00	18	15	2
R1003	SM08-01	CDB_001	f	50.00	16	20	6
R1004	SM08-01	CDB_001	m	59.00	19	20	3
R1005	SM08-01	CDB_001	f	56.00	16	30	5
R1006	SM08-01	CDB_001	f	51.00	18	20	4
R1007	SM08-01	CDB_001	f	49.00	17	20	3
R1008	SM08-01	CDB_001	f	61.00	16	30	7
R1009	SM08-01	CDB_001	f	62.00	18	15	5
R1010	SM08-01	CDB_001	m	42.00	20	20	3
R1011	SM08-01	CDB_001	m	54.00	16	20	5
R1012	SM08-01	CDB_001	f	50.00	15	20	6
R1013	SM08-01	CDB_001	m	47.00	16	20	6
R1014	SM08-01	CDB_001	f	53.00	27	30	6
R1015	SM08-01	CDB_001	f	40.00	13	15	5
R1016	SM08-01	CDB_001	m	25.00	14	30	8
R1017	SM08-01	CDB_001	f	47.00	19	10	4
R1018	SM08-01	CDB_001	f	43.00	13	20	8
R1019	SM08-01	CDB_001	m	42.00	16	20	6
R1020	SM08-01	CDB_001	m	27.00	15	28	7
R1021	SM08-01	CDB_001	f	33.00	15	20	7
R1022	SM08-01	CDB_001	f	33.00	15	20	3
R1023	SM08-01	CDB_001	m	48.00	18	20	5
R1024	SM08-01	CDB_001	f	38.00	20	25	8
R1025	SM08-01	CDB_001	f	46.00	12	20	7
R1026	SM08-01	CDB_001	f	41.00	16	20	9
R1027	SM08-01	CDB_001	f	64.00	19	20	6
R1028	SM08-01	CDB_001	f	42.00	24	20	3
R1029	SM08-01	CDB_001	f	34.00	14	25	8
R1030	SM08-01	CDB_001	f	62.00	20	15	2
R1031	SM08-01	CDB_001	f	63.00	14	12	3
R1032	SM08-01	CDB_001	f	35.00	15	20	2
R1033	SM08-01	CDB_001	f	40.00	15	10	5
R1034	SM08-01	CDB_001	m	56.00	17	10	5
R1035	SM08-01	CDB_001	m	58.00	20	30	8
R1036	SM08-01	CDB_001	f	44.00	17	40	8
R1037	SM08-01	CDB_001	m	62.00	17	40	9
R5001	SM08-01	CD_001	m	47.00	8	20	9
R5002	SM08-01	CD_001	f	31.00	18	20	6
R5003	SM08-01	CD_001	m	50.00	13	20	5
R5004	SM08-01	CD_001	f	33.00	18	15	6
R5005	SM08-01	CD_001	f	52.00	23	12	4
R5006	SM08-01	CD_001	f	50.00	18	20	9
R5007	SM08-01	CD_001	m	40.00	26	20	7
R5008	SM08-01	CD_001	f	54.00	21	20	6
R5009	SM08-01	CD_001	m	42.00	37	10	3
R5010	SM08-01	CD_001	f	58.00	20	30	5
R5011	SM08-01	CD_001	f	49.00	16	15	8
R5012	SM08-01	CD_001	f	56.00	15	60	8
R5013	SM08-01	CD_001	f	51.00	15	15	3
R5014	SM08-01	CD_001	m	46.00	19	10	6

**CONFIDENTIAL**

**Listing 1: Demographics, Smoking History, Fagerström Dependency Test (Baseline)**  
Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

(USA)

Subject ID	Study Identifier	Study Site ID	Sex	Age (Years)	Age Start Smoking	Average Cigarettes per day (previous year)	Fagerström Dependency Test
R5015	SM08-01	CD_001	f	61.00	18	30	5
R5016	SM08-01	CD_001	f	56.00	16	20	4
R5017	SM08-01	CD_001	f	58.00	51	10	4
R5018	SM08-01	CD_001	m	51.00	15	15	3
R5019	SM08-01	CD_001	m	44.00	15	25	7
R5020	SM08-01	CD_001	f	62.00	38	20	6
R5021	SM08-01	CD_001	f	33.00	23	12	3
R5022	SM08-01	CD_001	f	38.00	14	20	6
R5023	SM08-01	CD_001	f	48.00	24	12	0
R5024	SM08-01	CD_001	f	37.00	18	20	7
R5025	SM08-01	CD_001	m	57.00	21	40	9
R5026	SM08-01	CD_001	m	45.00	18	20	6
R5027	SM08-01	CD_001	f	34.00	21	13	4
R5028	SM08-01	CD_001	f	52.00	30	20	2
R3001	SM08-01	CP_001	f	29.00	15	15	4
R3002	SM08-01	CP_001	f	57.00	31	15	3
R3003	SM08-01	CP_001	m	50.00	18	20	5
R3004	SM08-01	CP_001	m	28.00	13	30	4
R3005	SM08-01	CP_001	f	59.00	18	18	5
R3006	SM08-01	CP_001	f	62.00	19	10	4
R3007	SM08-01	CP_001	m	33.00	18	20	9
R3008	SM08-01	CP_001	m	39.00	16	20	7
R3009	SM08-01	CP_001	f	63.00	18	18	5
R3010	SM08-01	CP_001	f	33.00	13	12	3
R3011	SM08-01	CP_001	f	44.00	15	20	5
R3012	SM08-01	CP_001	m	48.00	13	30	5
R3013	SM08-01	CP_001	m	36.00	22	18	5
R3014	SM08-01	CP_001	f	47.00	16	20	8
R3015	SM08-01	CP_001	f	43.00	21	20	6
R3016	SM08-01	CP_001	f	48.00	25	25	6
R3017	SM08-01	CP_001	f	30.00	17	10	0
R3018	SM08-01	CP_001	m	39.00	25	20	6
R3019	SM08-01	CP_001	f	50.00	13	15	7
R3020	SM08-01	CP_001	m	41.00	21	15	1
R3021	SM08-01	CP_001	m	53.00	9	45	9
R3022	SM08-01	CP_001	m	33.00	13	40	6
R3023	SM08-01	CP_001	f	62.00	29	15	3
R3024	SM08-01	CP_001	m	50.00	21	20	5
R3025	SM08-01	CP_001	f	38.00	13	15	5
R3026	SM08-01	CP_001	m	31.00	21	12	4
R3027	SM08-01	CP_001	f	29.00	12	30	6
R3028	SM08-01	CP_001	f	39.00	10	20	4
R3029	SM08-01	CP_001	f	64.00	13	20	7
R3030	SM08-01	CP_001	m	32.00	10	12	3
R3031	SM08-01	CP_001	f	39.00	15	15	7
R3032	SM08-01	CP_001	f	54.00	18	20	3
R2001	SM08-01	L0689282_2	m	30.00	18	15	3
R2002	SM08-01	L0689282_2	f	34.00	18	10	2
R2003	SM08-01	L0689282_2	f	38.00	17	20	7
R2004	SM08-01	L0689282_2	f	53.00	20	20	5
R2005	SM08-01	L0689282_2	m	44.00	17	11	5

**CONFIDENTIAL**

**Listing 1: Demographics, Smoking History, Fagerström Dependency Test (Baseline)**  
Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials

(USA)

Subject ID	Study Identifier	Study Site ID	Sex	Age (Years)	Age Start Smoking	Average Cigarettes per day (previous year)	Fagerström Dependency Test
R2006	SM08-01	L0689282_2	f	38.00	14	25	7
R2007	SM08-01	L0689282_2	m	55.00	16	20	5
R2008	SM08-01	L0689282_2	f	32.00	15	20	7
R2009	SM08-01	L0689282_2	m	28.00	14	30	9
R2010	SM08-01	L0689282_2	f	48.00	16	15	7
R2011	SM08-01	L0689282_2	f	51.00	17	20	5
R2012	SM08-01	L0689282_2	f	53.00	13	20	4
R2013	SM08-01	L0689282_2	f	46.00	20	10	4
R2014	SM08-01	L0689282_2	f	46.00	18	20	5
R2015	SM08-01	L0689282_2	f	32.00	15	20	6
R2016	SM08-01	L0689282_2	m	60.00	17	20	6
R2017	SM08-01	L0689282_2	f	47.00	12	20	6
R2018	SM08-01	L0689282_2	m	46.00	25	20	5
R2019	SM08-01	L0689282_2	m	28.00	17	20	5
R2020	SM08-01	L0689282_2	m	29.00	17	15	6
R2021	SM08-01	L0689282_2	f	57.00	17	20	2
R2022	SM08-01	L0689282_2	f	48.00	43	20	7
R2023	SM08-01	L0689282_2	f	30.00	25	15	3
R2024	SM08-01	L0689282_2	m	31.00	18	20	6
R2025	SM08-01	L0689282_2	m	29.00	19	15	2
R2026	SM08-01	L0689282_2	f	57.00	16	25	5
R2027	SM08-01	L0689282_2	f	60.00	15	30	6
R2028	SM08-01	L0689282_2	f	42.00	14	30	9
R2029	SM08-01	L0689282_2	f	61.00	15	50	9
R2030	SM08-01	L0689282_2	m	64.00	14	20	4
R2031	SM08-01	L0689282_2	f	29.00	13	15	6
R2032	SM08-01	L0689282_2	f	26.00	17	10	0
R4001	SM08-01	P3880_0342	m	50.00	17	30	8
R4002	SM08-01	P3880_0342	f	57.00	17	20	7
R4003	SM08-01	P3880_0342	m	63.00	18	10	8
R4004	SM08-01	P3880_0342	f	30.00	16	20	7
R4005	SM08-01	P3880_0342	m	41.00	17	21	5
R4006	SM08-01	P3880_0342	f	36.00	14	20	3
R4007	SM08-01	P3880_0342	f	37.00	17	20	7
R4008	SM08-01	P3880_0342	f	51.00	8	20	6
R4009	SM08-01	P3880_0342	f	29.00	20	10	5
R4010	SM08-01	P3880_0342	f	50.00	17	15	4
R4011	SM08-01	P3880_0342	f	47.00	20	30	9
R4012	SM08-01	P3880_0342	f	53.00	21	15	3
R4013	SM08-01	P3880_0342	f	52.00	16	20	7
R4014	SM08-01	P3880_0342	f	31.00	18	20	7
R4015	SM08-01	P3880_0342	f	57.00	19	20	6
R4016	SM08-01	P3880_0342	m	28.00	16	20	5
R4017	SM08-01	P3880_0342	f	49.00	21	21	8
R4018	SM08-01	P3880_0342	f	27.00	17	20	7
R4019	SM08-01	P3880_0342	f	43.00	17	13	7
R4020	SM08-01	P3880_0342	m	40.00	16	20	6
R4021	SM08-01	P3880_0342	f	52.00	18	30	7
R4022	SM08-01	P3880_0342	f	27.00	18	12	5
R4023	SM08-01	P3880_0342	f	51.00	25	15	5
R4024	SM08-01	P3880_0342	m	30.00	11	13	8

**CONFIDENTIAL**

**Listing 1: Demographics, Smoking History, Fagerström Dependency Test (Baseline)**  
Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials

(USA)

Subject ID	Study Identifier	Study Site ID	Sex	Age (Years)	Age Start Smoking	Average Cigarettes per day (previous year)	Fagerström Dependency Test
R4025	SM08-01	P3880_0342	m	54.00	16	40	8
R4026	SM08-01	P3880_0342	m	60.00	18	10	6
R4027	SM08-01	P3880_0342	m	44.00	22	20	5
R4028	SM08-01	P3880_0342	f	49.00	18	40	10
R4029	SM08-01	P3880_0342	m	48.00	15	18	6
R4030	SM08-01	P3880_0342	m	47.00	42	15	7
R4031	SM08-01	P3880_0342	f	50.00	13	20	5
R4032	SM08-01	P3880_0342	f	33.00	15	15	4
R4033	SM08-01	P3880_0342	f	49.00	29	20	8
R4034	SM08-01	P3880_0342	m	45.00	20	10	4
R4035	SM08-01	P3880_0342	f	45.00	13	20	7
R4036	SM08-01	P3880_0342	m	31.00	13	10	6
R4037	SM08-01	P3880_0342	m	43.00	12	10	4
R4038	SM08-01	P3880_0342	m	58.00	19	30	5
R4039	SM08-01	P3880_0342	f	60.00	12	30	10
R4040	SM08-01	P3880_0342	f	59.00	13	40	9
R4041	SM08-01	P3880_0342	f	55.00	46	20	5
R4042	SM08-01	P3880_0342	m	58.00	13	20	6
R4043	SM08-01	P3880_0342	f	55.00	15	30	4
R4044	SM08-01	P3880_0342	f	29.00	19	30	6
R4045	SM08-01	P3880_0342	f	45.00	14	16	4
R4046	SM08-01	P3880_0342	m	57.00	20	20	8
R4047	SM08-01	P3880_0342	m	47.00	16	24	8
R4048	SM08-01	P3880_0342	f	60.00	25	15	6
R4049	SM08-01	P3880_0342	f	40.00	15	20	7
R4050	SM08-01	P3880_0342	f	50.00	16	30	8
R4051	SM08-01	P3880_0342	m	50.00	19	10	1
R4052	SM08-01	P3880_0342	m	63.00	20	20	3
R4053	SM08-01	P3880_0342	f	38.00	17	20	6
R4054	SM08-01	P3880_0342	m	44.00	13	30	7
R4055	SM08-01	P3880_0342	m	31.00	18	20	2
R4056	SM08-01	P3880_0342	f	47.00	22	20	6
R4057	SM08-01	P3880_0342	f	49.00	24	20	6
R4058	SM08-01	P3880_0342	f	55.00	17	30	9
R4059	SM08-01	P3880_0342	m	56.00	18	30	4
R4060	SM08-01	P3880_0342	m	55.00	16	30	8
R4061	SM08-01	P3880_0342	f	51.00	11	25	9
R4062	SM08-01	P3880_0342	m	44.00	16	20	3
R4063	SM08-01	P3880_0342	m	58.00	20	15	2
R4064	SM08-01	P3880_0342	m	49.00	18	20	5
R4065	SM08-01	P3880_0342	f	27.00	20	20	6
R4066	SM08-01	P3880_0342	f	51.00	21	10	2
R4067	SM08-01	P3880_0342	f	45.00	14	20	7
R4068	SM08-01	P3880_0342	f	46.00	16	25	7
R4069	SM08-01	P3880_0342	m	55.00	17	20	3
R4070	SM08-01	P3880_0342	m	28.00	17	20	5
R4071	SM08-01	P3880_0342	m	25.00	21	20	7
R4072	SM08-01	P3880_0342	m	49.00	16	30	5
R4073	SM08-01	P3880_0342	f	55.00	20	20	7
R4074	SM08-01	P3880_0342	m	28.00	22	12	2
R4075	SM08-01	P3880_0342	m	35.00	15	25	9

**CONFIDENTIAL**

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on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

**(USA)**

Subject ID	Study Identifier	Study Site ID	Sex	Age (Years)	Age Start Smoking	Average Cigarettes per day (previous year)	Fagerström Dependency Test
R4076	SM08-01	P3880_0342	f	38.00	13	35	10
R4077	SM08-01	P3880_0342	f	41.00	23	23	10
R4078	SM08-01	P3880_0342	m	42.00	20	30	8
R4079	SM08-01	P3880_0342	f	29.00	14	15	6
R4080	SM08-01	P3880_0342	m	34.00	23	20	6
R4081	SM08-01	P3880_0342	f	62.00	34	10	3
R4082	SM08-01	P3880_0342	m	51.00	13	20	9
R4083	SM08-01	P3880_0342	m	55.00	20	30	9
R4084	SM08-01	P3880_0342	f	44.00	9	20	8
R4085	SM08-01	P3880_0342	m	37.00	32	20	3
R4086	SM08-01	P3880_0342	f	61.00	21	20	5
R4087	SM08-01	P3880_0342	f	63.00	45	20	7
R4088	SM08-01	P3880_0342	f	26.00	15	20	3
R4089	SM08-01	P3880_0342	m	52.00	17	15	5
R4090	SM08-01	P3880_0342	f	47.00	17	20	6
R4091	SM08-01	P3880_0342	f	30.00	14	18	5
R4092	SM08-01	P3880_0342	m	49.00	14	60	9
R4093	SM08-01	P3880_0342	m	50.00	40	15	6
R4094	SM08-01	P3880_0342	f	53.00	25	12	5
R4095	SM08-01	P3880_0342	m	34.00	16	20	10
R4096	SM08-01	P3880_0342	f	25.00	17	13	2
R4097	SM08-01	P3880_0342	m	63.00	10	23	8
R4098	SM08-01	P3880_0342	f	28.00	20	20	6
R4099	SM08-01	P3880_0342	m	27.00	17	15	7
R4100	SM08-01	P3880_0342	m	39.00	20	12	6
R4101	SM08-01	P3880_0342	m	26.00	18	15	3
R4102	SM08-01	P3880_0342	f	46.00	18	10	3
R4103	SM08-01	P3880_0342	m	27.00	18	13	4
R4104	SM08-01	P3880_0342	m	44.00	14	30	6
R4105	SM08-01	P3880_0342	m	53.00	16	20	6
R4106	SM08-01	P3880_0342	m	42.00	14	11	5
R4107	SM08-01	P3880_0342	f	41.00	15	20	5
R4108	SM08-01	P3880_0342	m	32.00	24	15	2
R4109	SM08-01	P3880_0342	m	44.00	19	20	5
R4110	SM08-01	P3880_0342	f	41.00	21	10	5
R4111	SM08-01	P3880_0342	f	33.00	25	20	4
R4112	SM08-01	P3880_0342	f	28.00	16	10	3
R4113	SM08-01	P3880_0342	f	36.00	15	15	5
R4114	SM08-01	P3880_0342	f	61.00	49	15	4
R4115	SM08-01	P3880_0342	m	42.00	18	35	6
R4116	SM08-01	P3880_0342	m	61.00	16	20	4
R4117	SM08-01	P3880_0342	f	46.00	19	20	5
R4118	SM08-01	P3880_0342	f	30.00	13	20	2
R4119	SM08-01	P3880_0342	f	42.00	16	30	7
R4120	SM08-01	P3880_0342	f	49.00	21	20	6
R4121	SM08-01	P3880_0342	f	31.00	14	20	8

**CONFIDENTIAL**

**Listing 2: Previous use of NRT, Other Pharmaceuticals, Other cessation aids and Quit Attempts**  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials

**(Serbia)**

<b>Subject ID</b>	<b>Group</b>	<b>Ever used NRT</b>	<b>Ever used other Pharmaceuticals</b>	<b>Ever used other cessation products</b>	<b>Previous quit attempts</b>
1001	Placebo	No	No	No	1
1002	Placebo	No	No	No	0
1003	Active	No	No	No	0
1004	Active	No	No	No	1
1005	Active	No	No	No	0
1006	Placebo	No	No	No	2
1007	Active	No	No	No	1
1008	Active	No	Yes	No	1
1009	Placebo	No	No	No	0
1010	Placebo	No	No	No	0
1011	Active	No	No	No	0
1012	Placebo	No	No	No	0
1013	Active	No	No	No	0
1014	Active	No	No	No	0
1015	Active	No	No	No	0
1016	Placebo	No	No	No	0
1017	Placebo	No	No	No	0
1018	Placebo	No	No	No	1
1019	Active	No	No	No	0
1020	Placebo	No	No	No	0
1021	Active	No	No	No	0
1022	Placebo	No	No	No	0
1023	Active	No	No	No	0
1024	Placebo	No	No	No	2
1025	Placebo	Yes	No	No	1
1026	Placebo	No	No	No	0
1027	Placebo	No	No	No	0
1028	Active	No	No	No	0
1029	Active	No	No	No	0
1030	Active	No	No	No	0
1031	Active	Yes	No	No	1
1032	Active	No	No	No	1
1033	Placebo	Yes	No	No	1
1034	Active	No	No	No	1
1035	Placebo	No	No	No	0
1036	Placebo	No	No	No	0
1037	Placebo	No	No	No	0
1038	Active	No	No	No	1
1039	Placebo	No	No	No	1
1040	Active	No	No	No	0
1041	Placebo	No	No	No	0
1042	Active	No	No	No	0
1043	Placebo	No	No	No	1
1044	Active	No	No	No	0
1045	Active	No	No	No	1
1046	Placebo	No	No	No	1
1047	Active	No	No	No	0
1048	Placebo	No	No	No	0
1049	Placebo	No	No	No	0
1050	Active	No	No	No	3
1205	Placebo	No	No	No	0

**CONFIDENTIAL**

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(Serbia)

Subject ID	Group	Ever used NRT	Ever used other Pharmaceuticals	Ever used other cessation products	Previous quit attempts
1206	Placebo	No	No	No	0
1207	Active	No	No	No	0
1208	Active	No	No	No	0
1209	Active	No	No	No	0
1210	Placebo	No	No	No	0
1211	Active	No	No	No	0
1212	Active	No	No	No	0
1213	Placebo	No	Yes	No	1
1214	Placebo	No	No	No	0
1215	Active	No	No	No	0
1216	Placebo	No	No	No	0
1217	Active	No	No	No	0
1218	Active	No	No	No	0
1219	Active	No	No	No	0
1220	Placebo	No	No	No	0
1221	Placebo	No	No	No	0
1222	Placebo	No	No	No	0
1223	Active	No	No	No	0
1224	Placebo	No	No	No	0
1225	Active	No	No	No	2
1226	Placebo	No	No	No	0
1227	Active	No	No	No	0
1228	Placebo	No	No	No	0
1229	Placebo	No	No	No	0
1230	Placebo	No	No	No	1
1231	Placebo	No	No	No	0
1232	Active	No	No	No	1
1233	Active	No	No	No	1
1234	Active	No	No	No	1
1235	Active	No	No	No	0
1236	Active	No	No	No	0
1237	Placebo	No	No	No	0
1238	Active	No	No	No	0
1239	Placebo	No	No	No	0
1240	Placebo	No	No	No	0
1241	Placebo	No	No	No	0
1242	Active	No	No	No	0
1243	Placebo	No	No	No	0
1244	Active	No	No	No	0
1245	Placebo	No	No	No	0
1246	Active	No	No	No	1
1247	Placebo	No	No	No	0
1325	Placebo	No	No	No	2
1326	Placebo	No	No	No	0
1327	Active	No	No	No	0
1328	Active	No	No	No	0
1329	Active	No	No	No	3
1330	Placebo	No	No	No	1
1331	Active	No	No	No	0
1332	Active	No	No	No	0
1333	Placebo	No	No	No	4

**CONFIDENTIAL**

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(Serbia)

<b>Subject ID</b>	<b>Group</b>	<b>Ever used NRT</b>	<b>Ever used other Pharmaceuticals</b>	<b>Ever used other cessation products</b>	<b>Previous quit attempts</b>
1334	Placebo	No	No	No	0
1335	Active	No	No	No	1
1336	Placebo	No	No	No	1
1337	Active	No	No	No	0
1338	Active	No	No	No	0
1339	Active	No	No	No	1
1340	Placebo	No	No	No	0
1341	Placebo	No	No	No	0
1342	Placebo	No	No	No	0
1343	Active	No	No	No	0
1344	Placebo	No	No	No	0
1345	Active	No	No	No	0
1346	Placebo	No	No	No	0
1347	Active	No	No	No	0
1348	Placebo	No	No	No	0
1349	Placebo	No	No	No	0
2001	Placebo	No	No	No	0
2002	Placebo	No	No	No	0
2003	Active	No	No	No	0
2004	Active	No	No	No	0
2005	Active	No	No	No	0
2006	Placebo	No	No	No	0
2007	Active	No	No	No	0
2008	Active	No	No	No	0
2009	Placebo	No	No	No	0
2010	Placebo	No	No	No	0
2011	Active	No	No	No	0
2012	Placebo	No	No	No	0
2013	Active	No	No	No	0
2014	Active	No	No	No	0
2015	Active	No	No	No	0
2016	Placebo	No	No	No	1
2017	Placebo	No	No	No	0
2018	Placebo	No	No	No	0
2019	Active	No	No	No	0
2020	Placebo	No	No	No	1
2021	Active	No	No	No	0
2022	Placebo	No	No	No	0
2023	Active	No	No	No	0
2024	Placebo	No	No	No	0
2025	Placebo	No	No	No	0
2026	Placebo	No	No	No	0
2027	Placebo	No	No	No	0
2028	Active	No	No	No	0
2029	Active	No	No	No	1
2030	Active	No	No	No	1
2031	Active	No	No	No	0
2032	Active	No	No	No	1
2033	Placebo	No	No	No	3
2034	Active	No	No	No	5
2035	Placebo	No	No	No	1

**CONFIDENTIAL**

**Listing 2: Previous use of NRT, Other Pharmaceuticals, Other cessation aids and Quit Attempts**

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(Serbia)

Subject ID	Group	Ever used NRT	Ever used other Pharmaceuticals	Ever used other cessation products	Previous quit attempts
2036	Placebo	No	No	No	0
2037	Placebo	No	No	No	1
2038	Active	No	No	No	0
2039	Placebo	No	No	No	0
2040	Active	No	No	No	1
2041	Placebo	No	No	No	0
2042	Active	No	No	No	4
2043	Placebo	No	No	No	0
2044	Active	No	No	No	0
2045	Active	No	No	No	0
2046	Placebo	No	No	No	3
2047	Active	No	No	No	0
2048	Placebo	No	Yes	No	1
2049	Placebo	No	No	No	2
2050	Active	No	No	No	0
2205	Active	No	No	No	2
2206	Placebo	No	No	No	0
2207	Placebo	No	No	No	0
2208	Active	No	No	No	2
2209	Active	No	No	No	1
2210	Placebo	No	No	No	3
2211	Placebo	No	Yes	No	3
2212	Placebo	No	No	No	0
2213	Active	No	No	No	1
2214	Active	No	No	No	1
2215	Active	No	No	No	0
2216	Placebo	No	No	No	4
2217	Active	No	No	No	0
2218	Placebo	No	No	No	0
2219	Active	No	No	No	0
2220	Placebo	No	No	No	1
2221	Placebo	No	No	No	0
2222	Active	No	No	No	0
2223	Placebo	No	No	No	1
2224	Placebo	No	No	No	0
2225	Placebo	No	No	No	2
2226	Active	No	No	No	0
2227	Active	No	No	No	0
2228	Active	No	No	No	0
2229	Placebo	No	No	No	1
2230	Active	No	No	No	0
2231	Active	No	No	No	2
2232	Placebo	No	No	No	0
2233	Placebo	No	No	No	0
2234	Active	No	No	No	0
2235	Placebo	No	No	No	0
2236	Placebo	No	No	No	1
2237	Placebo	No	No	No	0
2238	Active	No	No	No	2
2239	Active	No	No	No	0
2240	Active	No	No	No	1

**CONFIDENTIAL**

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**(Serbia)**

<b>Subject ID</b>	<b>Group</b>	<b>Ever used NRT</b>	<b>Ever used other Pharmaceuticals</b>	<b>Ever used other cessation products</b>	<b>Previous quit attempts</b>
2241	Active	No	No	No	0
2242	Active	No	No	No	1
2243	Placebo	No	No	No	0
2244	Placebo	No	No	No	1
2245	Active	No	No	No	0
2246	Placebo	No	No	No	0
2247	Active	No	No	No	1
2248	Active	No	No	No	1
2249	Placebo	No	No	No	0
2250	Placebo	No	No	No	0
2251	Active	No	No	No	0
2252	Placebo	No	No	No	0
2253	Active	No	No	No	2
2254	Placebo	No	No	No	2
2255	Active	No	No	No	1
2256	Placebo	No	No	No	1
2257	Active	No	No	No	0
2258	Placebo	No	No	No	10
2259	Placebo	No	No	No	0
2260	Placebo	No	No	No	0
2261	Active	No	No	No	1
2262	Active	No	No	No	0
2263	Placebo	No	No	No	0
2264	Active	No	No	No	0
2265	Active	No	No	No	0
2266	Active	No	No	No	3
2267	Active	No	No	No	0
2268	Placebo	No	No	No	6
2269	Placebo	No	No	No	0
2270	Placebo	No	No	No	1
2271	Placebo	No	No	No	0
2272	Placebo	No	No	No	1
2273	Active	No	No	No	0
2274	Placebo	No	No	No	0
2275	Active	No	No	No	0
2276	Active	No	No	No	1
2277	Active	No	No	No	0
2278	Active	No	No	No	0
2279	Placebo	No	No	No	1
2280	Placebo	No	No	No	1
2281	Active	No	No	No	0
2282	Placebo	No	No	No	0
2283	Placebo	No	No	No	0
2284	Active	No	No	No	0
2285	Active	No	No	No	0
2286	Placebo	No	No	No	1
2287	Active	No	No	No	0
2288	Placebo	No	No	No	1
2289	Active	No	No	No	0
2290	Placebo	No	No	No	0
2291	Active	No	No	No	0

**CONFIDENTIAL**

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<b>Subject ID</b>	<b>Group</b>	<b>Ever used NRT</b>	<b>Ever used other Pharmaceuticals</b>	<b>Ever used other cessation products</b>	<b>Previous quit attempts</b>
2292	Placebo	No	No	No	1
2293	Placebo	No	No	No	0
2294	Active	No	No	No	0
2295	Active	No	No	No	0
2296	Active	No	No	No	1
2297	Placebo	No	No	No	0
2298	Placebo	No	No	No	0
2299	Active	No	No	No	6
2300	Placebo	No	No	No	0
2301	Active	No	No	No	0
2302	Placebo	No	No	No	0
2303	Active	No	No	No	1
2304	Placebo	No	No	No	0
2305	Placebo	No	No	No	0
2306	Active	No	No	No	1
3001	Placebo	No	No	No	1
3002	Placebo	No	No	No	1
3003	Active	No	No	No	1
3004	Active	No	No	No	2
3006	Placebo	No	No	No	1
3007	Active	No	No	No	2
3008	Active	No	No	No	0
3009	Placebo	No	No	No	1
3010	Placebo	No	No	No	1
3011	Active	No	No	No	5
3012	Placebo	No	No	Yes	6
3013	Active	No	No	No	1
3014	Active	No	No	No	0
3015	Active	No	No	No	0
3016	Placebo	No	No	No	0
3017	Placebo	No	No	No	0
3018	Placebo	No	No	No	1
3019	Active	No	No	No	3
3020	Placebo	No	No	No	0
3021	Active	No	No	No	0
3022	Placebo	No	No	No	1
3023	Active	No	No	No	0
3024	Placebo	No	No	No	0
3025	Placebo	No	No	No	0
3026	Placebo	No	No	No	2
3027	Placebo	No	No	No	1
3028	Active	No	No	No	5
3029	Active	No	No	No	0
3030	Active	No	No	No	0
3031	Active	No	No	No	2
3032	Active	No	No	No	5
3033	Placebo	No	No	No	1
3034	Active	No	No	No	3
3035	Placebo	No	No	No	1
3036	Placebo	No	No	No	2
3037	Placebo	No	No	No	1

**CONFIDENTIAL**

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**(Serbia)**

<b>Subject ID</b>	<b>Group</b>	<b>Ever used NRT</b>	<b>Ever used other Pharmaceuticals</b>	<b>Ever used other cessation products</b>	<b>Previous quit attempts</b>
3038	Active	No	No	No	1
3039	Placebo	No	No	No	0
3040	Active	No	No	No	0
3041	Placebo	No	No	No	0
3042	Active	No	No	No	0
3043	Placebo	No	No	No	0
3044	Active	No	No	No	0
3045	Active	No	No	No	10
3046	Placebo	No	No	No	0
3047	Active	No	No	No	3
3048	Placebo	No	No	No	1
3049	Placebo	No	No	No	1
3050	Active	No	No	No	1

**CONFIDENTIAL**

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Subject ID	Group	Times used NRT	Number other pharmaceuticals	Times other cessation aids	Times other methods	Previous quit attempt
R1001	Active	.	.	2	2	Yes
R1002	Placebo	.	.	.	2	Yes
R1003	Active	1	2	3	.	Yes
R1004	Placebo	7	.	.	.	Yes
R1005	Active	5	1	3	6	Yes
R1006	Placebo	.	.	.	1	Yes
R1007	Active	.	.	.	3	Yes
R1008	Placebo	11	2	1	.	Yes
R1009	Active	2	.	4	.	Yes
R1010	Active	2	.	.	.	Yes
R1011	Placebo	.	1	.	2	Yes
R1012	Placebo	.	.	.	2	Yes
R1013	Placebo	.	1	.	.	Yes
R1014	Placebo	.	.	.	.	No
R1015	Active	.	.	.	.	No
R1016	Active	.	.	.	.	No
R1017	Active	.	.	.	.	No
R1018	Placebo	06	02	02	.	Yes
R1019	Active	.	.	.	1	Yes
R1020	Placebo	.	.	.	10	Yes
R1021	Placebo	1	1	.	.	Yes
R1022	Active	.	.	.	1	Yes
R1023	Placebo	4	1	UNK	7	Yes
R1024	Active	.	.	.	1	Yes
R1025	Active	6	3	2	4	Yes
R1026	Active	.	.	.	.	No
R1027	Placebo	.	.	.	2	Yes
R1028	Placebo	.	.	.	1	Yes
R1029	Active	2	1	.	.	Yes
R1030	Placebo	3	2	1	.	Yes
R1031	Active	1	.	1	2	Yes
R1032	Active	.	.	.	1	Yes
R1033	Placebo	.	1	1	.	Yes
R1034	Placebo	.	.	.	.	No
R1035	Active	1	.	.	.	Yes
R1036	Placebo	.	2	.	.	Yes
R1037	Active	3	.	.	.	Yes
R5001	Placebo	.	.	.	1	Yes
R5002	Active	.	.	.	1	Yes
R5003	Placebo	.	.	.	.	No
R5004	Active	1	.	.	6	Yes
R5005	Placebo	.	1	.	.	Yes
R5006	Active	.	2	1	5	Yes
R5007	Active	.	.	.	1	Yes
R5008	Placebo	3	1	.	.	Yes
R5009	Placebo	.	.	.	.	No
R5010	Active	.	.	.	1	Yes
R5011	Active	.	.	.	.	No
R5012	Placebo	1	.	.	.	Yes
R5013	Active	.	.	.	2	Yes
R5014	Placebo	.	.	.	.	No

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**(USA)**

Subject ID	Group	Times used NRT	Number other pharmaceuticals	Times other cessation aids	Times other methods	Previous quit attempt
R5015	Placebo	2	2	.	.	Yes
R5016	Placebo	4	2	.	.	Yes
R5017	Active	4	1	.	.	Yes
R5018	Active	3	.	.	2	Yes
R5019	Placebo	.	.	.	4	Yes
R5020	Active	1	2	.	.	Yes
R5021	Placebo	.	.	.	.	No
R5022	Active	1	3	.	.	Yes
R5023	Active	.	1	.	2	Yes
R5024	Placebo	.	.	.	.	No
R5025	Placebo	.	.	.	2	Yes
R5026	Placebo	.	.	.	1	Yes
R5027	Active	7	1	1	.	Yes
R5028	Active	2	2	.	.	Yes
R3001	Active	.	.	.	30	Yes
R3002	Placebo	1	1	.	.	Yes
R3003	Active	1	3	1	4	Yes
R3004	Placebo	1	.	.	2	Yes
R3005	Placebo	4	.	.	1	Yes
R3006	Active	.	.	.	.	No
R3007	Placebo	5	.	.	5	Yes
R3008	Placebo	2	.	.	2	Yes
R3009	Active	3	.	4	3	Yes
R3010	Placebo	1	.	.	2	Yes
R3011	Active	2	.	.	5	Yes
R3012	Active	3	1	.	6	Yes
R3013	Active	.	.	.	1	Yes
R3014	Placebo	.	.	.	.	No
R3015	Placebo	.	.	.	10	Yes
R3016	Active	.	.	.	1	Yes
R3017	Active	1	.	.	1	Yes
R3018	Placebo	.	.	.	2	Yes
R3019	Placebo	4	1	1	4	Yes
R3020	Active	2	.	.	6	Yes
R3021	Active	5	.	.	6	Yes
R3022	Placebo	5	2	.	5	Yes
R3023	Placebo	.	.	.	4	Yes
R3024	Active	.	.	.	.	No
R3025	Placebo	1	.	.	1	Yes
R3026	Active	5	2	.	1	Yes
R3027	Active	1	1	.	4	Yes
R3028	Placebo	.	.	.	.	No
R3029	Placebo	1	1	.	1	Yes
R3030	Active	.	.	.	1	Yes
R3031	Active	1	.	.	.	Yes
R3032	Placebo	.	.	.	2	Yes
R2001	Active	.	.	.	ONCE	Yes
R2002	Active	2	.	.	1	Yes
R2003	Active	1	OCCASION	.	MULTIPLE	Yes
R2004	Placebo	.	.	.	MULTIPLE	Yes
R2005	Placebo	.	1	.	2	Yes

**CONFIDENTIAL**

**Listing 2: Previous use of NRT, Other Pharmaceuticals, Other cessation aids and Quit Attempts**  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

**(USA)**

Subject ID	Group	Times used NRT	Number other pharmaceuticals	Times other cessation aids	Times other methods	Previous quit attempt
R2006	Placebo	2	.	MULTIPLE	1	Yes
R2007	Placebo	.	1	.	NUMEROUS	Yes
R2008	Active	.	.	.	1	Yes
R2009	Placebo	1	1	1	3	Yes
R2010	Active	.	2	.	.	Yes
R2011	Placebo	2	1	.	1	Yes
R2012	Active	3	1	3	1	Yes
R2013	Active	2	1	.	3	Yes
R2014	Placebo	.	1	.	2	Yes
R2015	Active	2	1	.	4	Yes
R2016	Placebo	3	.	.	1	Yes
R2017	Active	1	1	.	1	Yes
R2018	Placebo	1	.	.	1	Yes
R2019	Placebo	2	2	.	6	Yes
R2020	Active	1	1	.	4	Yes
R2021	Active	.	.	.	1	Yes
R2022	Placebo	1	1	.	1	Yes
R2023	Placebo	1	.	.	1	Yes
R2024	Active	.	1	.	4	Yes
R2025	Active	1	.	.	1	Yes
R2026	Active	2	2	2	5	Yes
R2027	Active	1	1	1	1	Yes
R2028	Placebo	1	1	.	3	Yes
R2029	Placebo	.	.	.	1	Yes
R2030	Placebo	1	.	.	1	Yes
R2031	Placebo	.	.	.	1	Yes
R2032	Active	.	.	.	1	Yes
R4001	Placebo	.	2	.	5	Yes
R4002	Active	.	.	2	2	Yes
R4003	Placebo	2	2	.	1	Yes
R4004	Active	.	.	.	3	Yes
R4005	Active	1	.	.	2	Yes
R4006	Placebo	2	.	.	.	Yes
R4007	Active	3	1	.	12	Yes
R4008	Active	2	1	6	.	Yes
R4009	Placebo	.	1	.	1	Yes
R4010	Placebo	.	1	.	1	Yes
R4011	Placebo	1	2	.	.	Yes
R4012	Active	1	.	1	4	Yes
R4013	Active	.	.	.	4	Yes
R4014	Placebo	2	1	.	6	Yes
R4015	Placebo	1	1	.	1	Yes
R4016	Active	1	.	.	2	Yes
R4017	Active	1	.	.	1	Yes
R4018	Placebo	.	.	.	1	Yes
R4019	Placebo	1	.	.	7	Yes
R4020	Active	1	.	1	.	Yes
R4021	Placebo	.	.	.	6	Yes
R4022	Active	.	.	.	1	Yes
R4023	Placebo	.	2	.	3	Yes
R4024	Active	.	.	.	12	Yes

**CONFIDENTIAL**

**Listing 2: Previous use of NRT, Other Pharmaceuticals, Other cessation aids and Quit Attempts**  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

**(USA)**

Subject ID	Group	Times used NRT	Number other pharmaceuticals	Times other cessation aids	Times other methods	Previous quit attempt
R4025	Active	4	3	.	.	Yes
R4026	Placebo	.	.	.	.	No
R4027	Active	.	.	.	3	Yes
R4028	Active	2	1	.	1	Yes
R4029	Placebo	4	1	.	14	Yes
R4030	Placebo	.	.	.	.	No
R4031	Placebo	5	3	.	.	Yes
R4032	Placebo	1	.	.	.	Yes
R4033	Active	1	.	.	.	Yes
R4034	Active	.	.	.	.	No
R4035	Active	1	.	.	.	Yes
R4036	Placebo	1	.	.	1	Yes
R4037	Placebo	.	.	.	4	Yes
R4038	Placebo	.	.	.	1	Yes
R4039	Active	.	1	.	.	Yes
R4040	Active	.	.	.	2	Yes
R4041	Placebo	1	1	.	3	Yes
R4042	Active	.	.	.	1	Yes
R4043	Active	1	.	1	1	Yes
R4044	Active	.	.	.	.	No
R4045	Placebo	.	1	.	1	Yes
R4046	Placebo	5	.	1	.	Yes
R4047	Placebo	.	.	.	2	Yes
R4048	Active	1	1	.	4	Yes
R4049	Active	2	.	.	.	Yes
R4050	Placebo	1	.	.	1	Yes
R4051	Active	.	.	.	.	No
R4052	Placebo	.	.	.	1	Yes
R4053	Active	1	2	.	10	Yes
R4054	Placebo	2	2	.	.	Yes
R4055	Active	1	.	1	1	Yes
R4056	Active	1	.	1	1	Yes
R4057	Active	2	.	.	5	Yes
R4058	Placebo	2	1	.	3	Yes
R4059	Placebo	.	1	.	1	Yes
R4060	Placebo	1	.	.	1	Yes
R4061	Active	1	2	1	.	Yes
R4062	Placebo	.	.	.	2	Yes
R4063	Active	1	.	.	6	Yes
R4064	Placebo	2	.	.	.	Yes
R4065	Active	.	.	.	1	Yes
R4066	Placebo	1	1	1	.	Yes
R4067	Placebo	7	2	.	7	Yes
R4068	Active	3	1	.	3	Yes
R4069	Active	.	2	1	.	Yes
R4070	Placebo	.	.	.	1	Yes
R4071	Active	1	.	.	.	Yes
R4072	Placebo	.	.	.	UNK	Yes
R4073	Active	2	1	2	6	Yes
R4074	Placebo	.	.	.	3	Yes
R4075	Active	2	1	.	.	Yes

**CONFIDENTIAL**

**Listing 2: Previous use of NRT, Other Pharmaceuticals, Other cessation aids and Quit Attempts**  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

**(USA)**

Subject ID	Group	Times used NRT	Number other pharmaceuticals	Times other cessation aids	Times other methods	Previous quit attempt
R4076	Placebo	1	2	.	.	Yes
R4077	Active	2	.	.	UNK	Yes
R4078	Placebo	1	.	.	6	Yes
R4079	Placebo	.	.	.	.	No
R4080	Active	1	.	.	.	Yes
R4081	Active	1	.	1	1	Yes
R4082	Placebo	.	1	.	50	Yes
R4083	Active	.	1	.	.	Yes
R4084	Placebo	1	.	.	1	Yes
R4085	Active	.	.	.	.	No
R4086	Active	.	.	.	2	Yes
R4087	Placebo	.	.	.	.	No
R4088	Placebo	.	.	.	.	No
R4089	Placebo	4	1	1	.	Yes
R4090	Active	4	.	1	.	Yes
R4091	Active	.	.	.	4	Yes
R4092	Active	.	.	.	UNK	Yes
R4093	Placebo	.	.	.	.	No
R4094	Placebo	1	.	.	MANY	Yes
R4095	Active	.	.	.	.	No
R4096	Placebo	.	.	.	5	Yes
R4097	Active	UNK	2	.	1	Yes
R4098	Placebo	.	1	.	.	Yes
R4099	Active	.	.	.	1	Yes
R4100	Active	.	.	1	1	Yes
R4101	Placebo	.	.	.	2	Yes
R4102	Placebo	.	.	.	2	Yes
R4103	Placebo	.	1	.	.	Yes
R4104	Placebo	.	.	.	.	No
R4105	Active	.	.	.	.	No
R4106	Active	.	.	.	UNK	Yes
R4107	Active	2	2	.	.	Yes
R4108	Placebo	.	.	.	UNK	Yes
R4109	Placebo	5	.	.	.	Yes
R4110	Active	2	.	1	.	Yes
R4111	Placebo	.	.	.	.	No
R4112	Active	.	.	.	5	Yes
R4113	Active	3	.	.	1	Yes
R4114	Placebo	2	.	1	.	Yes
R4115	Active	1	.	.	.	Yes
R4116	Placebo	.	.	.	3	Yes
R4117	Active	.	1	.	.	Yes
R4118	Placebo	.	.	.	1	Yes
R4119	Placebo	.	.	.	.	No
R4120	Active	.	.	.	3	Yes
R4121	Placebo	1	1	.	3	Yes

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**Listing 3: Expired Air CO (ppm)**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**(Serbia)**

<b>Subject ID</b>	<b>Group</b>	<b>week 0</b>	<b>week 2</b>	<b>week 6</b>	<b>week 12</b>	<b>week 18</b>	<b>week 24</b>	<b>week 30</b>	<b>week 36</b>	<b>week 42</b>	<b>week 48</b>
1001	Placebo	25	26	30	34	32	20	.	18	.	.
1002	Placebo	17	20	28	18	27	9	22	18	12	11
1003	Active	35	8	3	8	28	11	6	.	.	.
1004	Active	15	10	8	17	.	.	.	.	.	.
1005	Active	15	20	12	9	13	12	9	14	7	.
1006	Placebo	13	17	11	13	11	17	.	.	.	.
1007	Active	26	21	.	.	.	.	.	.	.	.
1008	Active	40	30	30	25	30	27	25	27	22	19
1009	Placebo	27	38	36	19	50	24	29	26	13	13
1010	Placebo	19	21	26	20	20	25	.	.	.	.
1011	Active	30	30	26	68	44	38	.	.	.	.
1012	Placebo	38	46	34	23	21	29	.	.	.	.
1013	Active	15	11	13	13	19	14	.	.	.	.
1014	Active	15	11	15	25	26	22	.	.	.	25
1015	Active	28	18	20	29	23	.	.	.	.	33
1016	Placebo	58	28	14	28	29	21	3	12	11	14
1017	Placebo	23	11	25	27	29	.	.	.	.	22
1018	Placebo	20	13	.	.	.	.	.	.	.	.
1019	Active	11	15	18	16	22	18	19	.	.	.
1020	Placebo	31	22	38	39	30	.	.	.	.	44
1021	Active	14	23	9	18	10	.	.	.	.	23
1022	Placebo	14	14	.	.	.	.	.	.	.	.
1023	Active	20	29	13	4	6	4	13	9	23	18
1024	Placebo	12	23	21	.	36	.	.	.	.	.
1025	Placebo	6	5	6	9	13	8	8	.	.	.
1026	Placebo	22	10	.	.	.	.	.	.	.	.
1027	Placebo	21	14	24	23	50	14	21	.	.	.
1028	Active	11	10	10	17	10	13	13	.	.	.
1029	Active	23	22	26	33	22	.	.	.	.	.
1030	Active	21	21	28	27	21	13	14	13	9	9
1031	Active	23	23	16	24	16	4	23	.	.	.
1032	Active	22	.	.	.	.	.	.	.	.	.
1033	Placebo	10	10	10	14	20	14	10	.	.	.
1034	Active	26	13	.	.	.	.	.	.	.	.
1035	Placebo	7	5	7	9	17	9	11	.	.	.
1036	Placebo	7	.	.	.	.	.	.	.	.	.
1037	Placebo	6	8	7	7	7	5	9	5	7	1
1038	Active	3	5	3	5	2	2	3	4	0	0
1039	Placebo	22	21	24	.	.	.	.	.	.	.
1040	Active	15	9	17	.	.	.	.	.	.	.
1041	Placebo	19	11	18	25	21	.	.	.	.	25
1042	Active	26	12	15	32	29	.	.	.	.	.
1043	Placebo	20	21	13	20	13	7	.	.	.	.
1044	Active	11	14	21	.	.	.	.	.	.	20
1045	Active	12	.	.	.	.	.	.	.	.	.
1046	Placebo	19	49	13	22	19	.	.	.	.	30
1047	Active	24	49	60	53	49	.	.	.	.	.
1048	Placebo	25	22	39	33	40	.	.	.	.	.
1049	Placebo	20	14	32	28	25	.	.	.	.	.
1050	Active	13	10	10	7	6	.	.	.	.	.
1205	Placebo	23	13	14	7	9	9	11	8	7	7

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**Listing 3: Expired Air CO (ppm)**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**(Serbia)**

<b>Subject ID</b>	<b>Group</b>	<b>week 0</b>	<b>week 2</b>	<b>week 6</b>	<b>week 12</b>	<b>week 18</b>	<b>week 24</b>	<b>week 30</b>	<b>week 36</b>	<b>week 42</b>	<b>week 48</b>
1206	Placebo	30	26	20	.	.	.	.	.	.	.
1207	Active	22	16	17	.	.	.	.	.	.	.
1208	Active	28	38	33	21	29	.	.	.	.	.
1209	Active	2	2	3	4	.	.	.	.	.	.
1210	Placebo	43	39	36	29	33	22	20	14	12	9
1211	Active	42	44	47	33	.	.	.	.	.	.
1212	Active	29	25	12	9	23	21	11	11	11	10
1213	Placebo	39	32	25	27	28	.	.	.	.	.
1214	Placebo	34	15	29	21	16	22	22	15	14	.
1215	Active	12	7	16	13	12	12	.	.	.	.
1216	Placebo	15	20	18	10	19	8	8	8	6	7
1217	Active	19	19	15	21	18	.	.	.	.	.
1218	Active	35	25	21	.	.	.	.	.	.	.
1219	Active	23	21	22	.	.	.	.	.	.	15
1220	Placebo	22	42	37	22	14	11	10	10	11	11
1221	Placebo	23	26	21	15	20	.	.	.	.	.
1222	Placebo	20	19	18	14	14	.	.	.	.	18
1223	Active	25	17	18	19	12	17	18	.	.	.
1224	Placebo	25	31	32	23	22	11	10	.	.	.
1225	Active	29	16	26	21	26	.	.	.	.	19
1226	Placebo	20	17	14	12	33	10	9	9	9	10
1227	Active	12	13	6	5	5	.	.	.	.	.
1228	Placebo	11	8	6	2	4	.	.	.	.	.
1229	Placebo	25	27	13	13	11	.	.	.	.	.
1230	Placebo	30	29	34	18	18	15	13	12	13	15
1231	Placebo	18	15	14	10	11	8	.	.	.	.
1232	Active	19	15	10	.	.	.	.	.	.	.
1233	Active	20	9	11	10	7	10	4	11	10	8
1234	Active	29	22	23	21	.	.	.	.	.	.
1235	Active	20	15	10	8	3	5	3	5	.	3
1236	Active	25	21	19	.	.	.	.	.	.	.
1237	Placebo	20	10	18	18	16	13	16	15	14	14
1238	Active	16	11	12	9	10	7	7	.	.	.
1239	Placebo	32	11	14	18	15	14	14	14	15	11
1240	Placebo	18	11	6	7	6	6	6	6	5	6
1241	Placebo	23	28	18	.	.	.	.	.	.	.
1242	Active	25	8	16	15	17	9	9	10	10	12
1243	Placebo	25	15	10	12	10	10	10	9	10	12
1244	Active	35	21	22	18	17	17	15	5	5	6
1245	Placebo	25	15	4	5	5	9	9	6	4	5
1246	Active	40	18	17	29	25	20	20	5	4	2
1247	Placebo	31	23	20	20	15	15	14	15	20	.
1325	Placebo	20	20	18	12	10	6	4	4	3	2
1326	Placebo	23	22	20	20	16	14	12	12	12	10
1327	Active	35	35	30	29	22	20	18	.	.	18
1328	Active	43	38	35	32	28	12	8	6	5	3
1329	Active	26	24	20	20	14	14	14	11	10	10
1330	Placebo	18	18	16	16	16	15	15	14	11	11
1331	Active	21	20	20	19	18	16	14	10	6	2
1332	Active	30	27	26	26	22	18	15	13	12	12
1333	Placebo	39	35	35	32	26	24	19	16	13	12

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**Listing 3: Expired Air CO (ppm)**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials

**(Serbia)**

Subject ID	Group	week 0	week 2	week 6	week 12	week 18	week 24	week 30	week 36	week 42	week 48
1334	Placebo	34	34	30	30	28	24	21	16	14	14
1335	Active	34	30	30	29	25	20	16	12	12	12
1336	Placebo	25	25	22	20	18	16	16	14	11	11
1337	Active	18	16	16	14	14	12	11	11	8	8
1338	Active	29	29	26	23	21	20	17	12	6	3
1339	Active	19	18	18	18	14	13	12	12	10	10
1340	Placebo	28	26	24	25	20	19	16	13	13	12
1341	Placebo	32	32	30	30	25	20	18	15	14	11
1342	Placebo	29	30	28	22	18	18	.	.	.	.
1343	Active	21	21	20	18	14	12	12	10	3	1
1344	Placebo	22	20	20	20	16	12	10	10	4	0
1345	Active	25	22	20	18	15	14	11	8	2	0
1346	Placebo	28	28	26	24	18	14	13	12	12	10
1347	Active	13	12	15	26	24	23	.	.	.	.
1348	Placebo	17	18	18	21	19	26	.	.	.	.
1349	Placebo	28	23	15	17	16	14	14	.	.	.
2001	Placebo	44	44	23	35	25	24	24	24	22	16
2002	Placebo	46	45	38	34	30	30	28	28	26	26
2003	Active	17	15	15	15	12	14	14	14	14	14
2004	Active	31	18	23	45	21	30	.	.	.	.
2005	Active	17	21	15	11	9	17	.	.	.	.
2006	Placebo	14	15	10	15	27	7	.	.	.	.
2007	Active	28	26	24	24	20	30	.	.	.	.
2008	Active	14	17	13	12	16	14	.	.	.	.
2009	Placebo	25	16	13	23	14	13	.	.	.	.
2010	Placebo	31	19	17	22	25	16	14	10	10	10
2011	Active	14	14	11	16	10	12	.	.	.	.
2012	Placebo	25	20	15	27	18	19	.	.	.	.
2013	Active	28	26	22	20	24	17	.	.	.	.
2014	Active	11	11	12	10	8	8	.	.	.	.
2015	Active	21	11	24	22	27	27	.	.	.	.
2016	Placebo	12	9	10	14	20	4	4	4	3	4
2017	Placebo	19	11	17	26	32	26	.	.	.	.
2018	Placebo	12	16	12	17	10	11	.	.	.	.
2019	Active	14	13	10	3	2	5	.	.	.	.
2020	Placebo	10	20	20	6	8	8	.	.	.	.
2021	Active	17	11	23	19	15	14	10	15	10	19
2022	Placebo	29	30	25	25	32	26	24	24	32	30
2023	Active	19	19	20	17	22	19	.	.	.	.
2024	Placebo	14	14	14	21	10	8	.	.	.	.
2025	Placebo	25	25	22	23	18	18	15	15	16	15
2026	Placebo	11	6	9	9	8	10	8	9	5	0
2027	Placebo	11	5	12	6	6	6	4	7	7	7
2028	Active	22	18	20	13	12	8	8	3	3	0
2029	Active	21	20	20	15	15	16	14	14	12	13
2030	Active	40	25	35	31	28	27	26	30	20	20
2031	Active	15	15	15	8	8	8	8	8	.	.
2032	Active	32	31	32	29	30	26	24	24	25	22
2033	Placebo	12	15	12	14	12	10	10	10	10	12
2034	Active	14	12	10	13	16	3	.	.	.	.
2035	Placebo	41	28	27	50	49	40	40	29	29	28

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**Listing 3: Expired Air CO (ppm)**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials

**(Serbia)**

<b>Subject ID</b>	<b>Group</b>	<b>week 0</b>	<b>week 2</b>	<b>week 6</b>	<b>week 12</b>	<b>week 18</b>	<b>week 24</b>	<b>week 30</b>	<b>week 36</b>	<b>week 42</b>	<b>week 48</b>
2036	Placebo	24	21	18	29	20	22	20	18	20	19
2037	Placebo	23	22	22	12	18	.	.	.	.	.
2038	Active	14	14	14	16	16	.	.	.	.	.
2039	Placebo	19	19	18	16	16	9	9	8	9	7
2040	Active	11	10	10	12	10	15	.	.	.	.
2041	Placebo	20	20	18	53	18	.	.	.	.	22
2042	Active	17	16	16	21	14	15	14	14	14	12
2043	Placebo	22	20	16	16	.	.	.	.	.	.
2044	Active	22	22	18	20	18	15	14	14	14	14
2045	Active	46	45	38	32	24	24	22	20	18	18
2046	Placebo	22	20	23	20	18	18	.	.	.	.
2047	Active	15	15	15	10	6	10	6	4	4	4
2048	Placebo	23	20	21	6	6	6	6	2	4	1
2049	Placebo	16	16	12	10	8	8	8	8	8	8
2050	Active	30	28	22	16	16	28	26	26	24	20
2205	Active	24	26	26	15	16	14	14	12	12	12
2206	Placebo	31	32	32	30	28	27	24	20	16	16
2207	Placebo	25	25	24	20	20	18	15	15	14	12
2208	Active	24	24	22	22	22	20	18	15	14	12
2209	Active	27	27	21	23	23	21	19	16	16	12
2210	Placebo	21	20	15	15	14	12	8	8	5	4
2211	Placebo	34	34	30	24	18	18	18	16	14	14
2212	Placebo	23	25	23	23	21	20	20	18	16	14
2213	Active	28	31	29	21	20	20	18	16	14	14
2214	Active	42	38	34	36	30	25	22	20	18	16
2215	Active	37	36	36	32	26	24	24	22	22	20
2216	Placebo	34	34	32	30	27	26	22	18	18	18
2217	Active	28	28	25	26	26	20	20	12	10	5
2218	Placebo	27	27	24	23	22	20	16	15	15	14
2219	Active	36	36	34	32	32	27	20	18	16	16
2220	Placebo	21	20	21	20	20	13	13	12	12	12
2221	Placebo	26	24	20	24	18	18	14	14	10	6
2222	Active	21	20	20	18	16	14	12	10	12	12
2223	Placebo	15	15	14	14	14	12	12	10	8	10
2224	Placebo	27	26	26	25	25	19	18	18	18	18
2225	Placebo	24	26	24	22	21	20	18	18	14	14
2226	Active	27	25	24	23	23	21	20	20	18	18
2227	Active	38	36	29	25	25	24	22	20	18	17
2228	Active	21	20	16	18	18	14	14	11	11	10
2229	Placebo	17	18	16	15	14	12	12	10	10	10
2230	Active	18	18	16	15	15	14	14	11	11	11
2231	Active	30	30	28	24	20	16	16	14	14	12
2232	Placebo	26	26	21	24	21	18	16	14	14	12
2233	Placebo	26	26	24	24	20	19	16	15	14	14
2234	Active	45	45	45	39	35	28	24	22	24	20
2235	Placebo	41	42	41	40	38	30	26	24	20	18
2236	Placebo	19	18	18	18	14	11	11	10	10	6
2237	Placebo	27	26	24	25	20	18	16	16	14	12
2238	Active	24	24	22	23	21	20	15	14	12	8
2239	Active	34	32	28	26	25	22	22	20	18	16
2240	Active	28	28	24	23	23	20	20	16	16	12

**CONFIDENTIAL**

**Listing 3: Expired Air CO (ppm)**

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**(Serbia)**

Subject ID	Group	week 0	week 2	week 6	week 12	week 18	week 24	week 30	week 36	week 42	week 48
2241	Active	37	35	32	30	28	26	24	20	18	18
2242	Active	34	34	30	25	25	18	16	10	8	1
2243	Placebo	29	28	26	25	21	20	18	16	16	12
2244	Placebo	26	26	20	18	18	14	14	14	14	14
2245	Active	11	11	10	10	10	3	3	4	4	2
2246	Placebo	19	18	17	16	14	13	13	12	14	12
2247	Active	15	13	12	11	9	10	9	7	8	7
2248	Active	28	26	24	24	20	16	14	14	20	18
2249	Placebo	28	28	26	26	24	20	18	15	15	11
2250	Placebo	16	16	14	15	12	11	11	10	8	6
2251	Active	22	24	22	20	16	16	14	14	13	10
2252	Placebo	20	20	18	16	15	12	12	12	11	11
2253	Active	28	26	26	27	22	22	18	16	13	12
2254	Placebo	39	36	38	26	20	18	16	16	16	16
2255	Active	17	14	16	19	21	20	.	.	.	.
2256	Placebo	27	26	17	17	15	14	14	12	5	2
2257	Active	42	32	36	1	1	0	1	0	0	2
2258	Placebo	26	26	25	20	18	16	16	14	10	8
2259	Placebo	24	24	22	20	18	16	12	10	8	4
2260	Placebo	26	24	24	22	18	17	16	14	12	10
2261	Active	14	14	17	14	12	11	.	.	.	.
2262	Active	11	12	11	11	13	1	0	1	1	1
2263	Placebo	23	20	25	29	23	30	.	.	.	.
2264	Active	23	17	17	14	16	16	.	.	.	.
2265	Active	36	36	32	32	28	24	20	20	16	14
2266	Active	25	24	24	22	22	20	16	15	15	12
2267	Active	45	44	40	38	36	30	26	20	18	14
2268	Placebo	17	17	23	16	14	12	.	.	.	.
2269	Placebo	17	17	23	12	15	12	.	.	.	.
2270	Placebo	18	16	20	15	13	1	2	1	4	3
2271	Placebo	21	17	19	14	14	12	11	7	9	8
2272	Placebo	29	26	27	30	32	27	.	.	.	.
2273	Active	27	28	24	22	27	29	.	.	.	.
2274	Placebo	17	17	14	15	13	11	12	10	7	17
2275	Active	18	17	15	15	12	1	2	0	2	2
2276	Active	15	16	18	13	17	17	.	.	.	.
2277	Active	12	12	19	11	6	6	2	1	3	1
2278	Active	24	22	27	15	17	21	.	.	.	.
2279	Placebo	31	28	33	38	34	29	16	13	16	19
2280	Placebo	32	28	17	9	9	7	7	9	11	8
2281	Active	20	18	18	27	14	14	.	.	.	.
2282	Placebo	24	22	19	20	17	15	17	17	13	15
2283	Placebo	34	36	29	27	27	27	.	.	.	.
2284	Active	24	22	41	30	32	36	.	.	.	.
2285	Active	12	13	14	9	8	14	.	.	.	.
2286	Placebo	14	13	17	22	19	21	.	.	.	.
2287	Active	19	16	17	14	14	12	14	16	13	.
2288	Placebo	40	33	28	29	27	15	.	.	.	.
2289	Active	30	31	16	15	17	19	21	25	21	.
2290	Placebo	28	24	17	14	16	13	17	19	15	.
2291	Active	23	27	21	24	27	17	14	16	13	.

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A meta-analysis of results from two randomized clinical trials

**(Serbia)**

<b>Subject ID</b>	<b>Group</b>	<b>week 0</b>	<b>week 2</b>	<b>week 6</b>	<b>week 12</b>	<b>week 18</b>	<b>week 24</b>	<b>week 30</b>	<b>week 36</b>	<b>week 42</b>	<b>week 48</b>
2292	Placebo	20	17	18	20	23	28	.	.	.	.
2293	Placebo	23	20	17	14	15	12	11	9	12	.
2294	Active	24	27	24	25	23	27	.	.	.	.
2295	Active	19	21	26	14	11	7	3	4	1	4
2296	Active	14	15	10	0	2	1	1	2	2	3
2297	Placebo	17	15	18	14	16	13	13	11	14	.
2298	Placebo	21	22	18	14	17	13	11	13	11	.
2299	Active	33	26	13	12	9	17	.	.	.	.
2300	Placebo	23	20	21	17	14	13	12	14	13	14
2301	Active	29	26	23	24	27	29	.	.	.	.
2302	Placebo	18	16	19	16	15	1	11	13	17	15
2303	Active	18	19	15	16	18	15	.	.	.	.
2304	Placebo	23	23	19	16	17	17	.	.	.	.
2305	Placebo	16	14	17	17	16	4	0	3	1	3
2306	Active	21	23	27	19	6	12	13	9	9	.
3001	Placebo	18	18	22	16	15	10	10	10	10	8
3002	Placebo	32	30	28	14	14	21	19	15	15	10
3003	Active	15	17	9	12	14	12	12	10	10	6
3004	Active	24	13	8	7	7	4	3	3	1	0
3006	Placebo	28	24	0	21	15	18	16	16	15	15
3007	Active	16	16	12	13	12	11	10	6	6	6
3008	Active	13	13	15	11	10	11	10	7	8	8
3009	Placebo	14	12	16	14	14	10	10	10	10	10
3010	Placebo	8	8	11	10	10	6	6	6	5	5
3011	Active	8	10	10	6	8	6	6	4	4	0
3012	Placebo	15	15	15	17	16	12	12	10	10	10
3013	Active	27	18	14	21	18	18	16	10	8	4
3014	Active	38	32	33	28	26	25	24	24	20	20
3015	Active	45	39	35	42	38	36	35	31	28	24
3016	Placebo	14	14	12	12	10	10	10	9	9	10
3017	Placebo	13	14	17	23	20	12	12	10	10	10
3018	Placebo	38	32	28	30	25	24	24	20	18	18
3019	Active	11	14	11	14	12	10	10	9	10	10
3020	Placebo	33	35	30	37	30	25	25	20	18	16
3021	Active	19	22	15	24	19	16	15	14	14	14
3022	Placebo	24	28	20	22	.	.	.	.	.	.
3023	Active	18	18	15	12	14	11	11	9	9	9
3024	Placebo	28	31	30	26	24	23	20	18	16	14
3025	Placebo	23	25	25	13	13	11	11	10	10	10
3026	Placebo	32	28	28	25	24	21	22	18	16	16
3027	Placebo	25	27	25	21	20	20	21	18	15	15
3028	Active	28	26	26	28	24	24	23	22	20	20
3029	Active	23	21	22	21	20	18	20	16	14	14
3030	Active	22	24	22	20	20	18	18	16	16	15
3031	Active	23	25	25	20	20	18	18	16	16	16
3032	Active	39	32	30	36	30	28	26	25	24	20
3033	Placebo	28	25	26	23	20	20	20	18	16	16
3034	Active	23	23	24	20	20	18	16	16	14	14
3035	Placebo	32	28	30	26	22	21	20	14	12	9
3036	Placebo	24	21	22	23	22	21	20	16	12	12
3037	Placebo	24	22	22	16	16	15	15	13	12	12

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3038	Active	26	26	24	24	24	18	9	0	0	1
3039	Placebo	21	18	20	16	12	15	14	12	10	10
3040	Active	32	30	32	28	26	26	22	20	18	24
3041	Placebo	24	24	24	20	20	18	18	16	14	14
3042	Active	25	25	27	22	20	20	19	18	18	18
3043	Placebo	17	17	16	12	12	10	10	8	8	8
3044	Active	18	20	18	15	15	13	13	12	10	10
3045	Active	21	22	20	20	18	17	16	15	12	12
3046	Placebo	35	34	35	30	29	28	26	22	18	18
3047	Active	24	24	22	22	21	20	19	16	14	14
3048	Placebo	20	20	20	18	18	16	16	15	12	10
3049	Placebo	16	15	16	14	12	12	10	8	8	8
3050	Active	24	24	22	21	20	18	18	10	8	4

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R1001	Active	19	0	5	2	10
R1002	Placebo	14	5	6	22	6
R1003	Active	13	.	.	13	.
R1004	Placebo	24	4	6	11	9
R1005	Active	37	12	22	19	18
R1006	Placebo	12	32	12	26	26
R1007	Active	23	25	0	4	18
R1008	Placebo	19	9	.	26	.
R1009	Active	32	3	.	19	.
R1010	Active	14	18	4	14	13
R1011	Placebo	11	9	7	9	6
R1012	Placebo	33	33	40	.	35
R1013	Placebo	10	4	6	3	8
R1014	Placebo	38	.	.	.	.
R1015	Active	21	19	7	29	12
R1016	Active	19	17	11	17	19
R1017	Active	30	7	10	8	15
R1018	Placebo	34	25	.	3	.
R1019	Active	26	9	10	.	12
R1020	Placebo	13	2	2	3	4
R1021	Placebo	27	8	30	21	20
R1022	Active	8	32	13	16	20
R1023	Placebo	33	.	.	32	.
R1024	Active	18	20	19	21	19
R1025	Active	10	2	1	1	0
R1026	Active	30	7	4	3	0
R1027	Placebo	17	.	.	31	.
R1028	Placebo	16	2	6	9	9
R1029	Active	23	2	.	.	.
R1030	Placebo	15	3	6	8	2
R1031	Active	16	0	.	5	0
R1032	Active	12	3	2	2	.
R1033	Placebo	41	.	.	11	.
R1034	Placebo	17	3	16	11	14
R1035	Active	32	12	19	16	22
R1036	Placebo	16	6	3	.	.
R1037	Active	27	.	15	16	3
R5001	Placebo	23	22	23	18	.
R5002	Active	18	0	3	27	10
R5003	Placebo	27	19	17	11	13
R5004	Active	23	3	10	9	11
R5005	Placebo	20	11	.	.	.
R5006	Active	34	11	19	13	29
R5007	Active	18	.	.	.	.
R5008	Placebo	24	11	18	12	11
R5009	Placebo	1	.	.	.	.
R5010	Active	23	.	.	24	.
R5011	Active	20	2	3	0	0
R5012	Placebo	31	.	.	44	.
R5013	Active	17	2	2	2	3
R5014	Placebo	13	19	11	.	12

**CONFIDENTIAL**

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R5015	Placebo	31	28	25	21	19
R5016	Placebo	36	.	.	31	.
R5017	Active	27	.	.	18	.
R5018	Active	25	27	26	24	22
R5019	Placebo	11	15	21	27	18
R5020	Active	21	14	25	20	21
R5021	Placebo	9	0	5	4	3
R5022	Active	17	9	4	15	10
R5023	Active	8	.	1	1	3
R5024	Placebo	30	.	.	.	.
R5025	Placebo	29	32	19	27	20
R5026	Placebo	40	.	.	.	.
R5027	Active	15	2	2	2	7
R5028	Active	30	.	13	16	13
R3001	Active	2	1	.	0	6
R3002	Placebo	25	0	0	0	0
R3003	Active	11	4	5	2	10
R3004	Placebo	9	17	18	3	1
R3005	Placebo	36	26	34	32	.
R3006	Active	8	6	6	4	5
R3007	Placebo	16	2	5	14	13
R3008	Placebo	25	0	2	2	0
R3009	Active	17	1	.	5	.
R3010	Placebo	14	0	2	2	1
R3011	Active	3	4	7	8	10
R3012	Active	25	.	.	15	.
R3013	Active	28	3	2	0	11
R3014	Placebo	59	39	.	45	.
R3015	Placebo	6	.	.	5	.
R3016	Active	24	20	22	24	18
R3017	Active	2	.	.	0	.
R3018	Placebo	20	0	.	.	.
R3019	Placebo	18	5	9	17	20
R3020	Active	18	3	1	2	2
R3021	Active	13	.	.	.	.
R3022	Placebo	23	23	.	19	18
R3023	Placebo	23	.	.	11	.
R3024	Active	7	.	.	6	.
R3025	Placebo	20	8	.	17	.
R3026	Active	15	3	0	0	1
R3027	Active	22	21	25	.	.
R3028	Placebo	10	4	7	8	6
R3029	Placebo	8	7	.	.	.
R3030	Active	21	.	.	.	.
R3031	Active	19	.	.	.	14
R3032	Placebo	19	.	.	.	.
R2001	Active	17	.	.	20	.
R2002	Active	7	2	1	1	1
R2003	Active	13	1	1	1	1
R2004	Placebo	17	.	.	11	.
R2005	Placebo	8	1	1	2	1

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R2006	Placebo	26	14	1	.	19
R2007	Placebo	23	9	10	12	4
R2008	Active	29	22	.	.	.
R2009	Placebo	38	1	4	8	4
R2010	Active	26	7	16	21	9
R2011	Placebo	36	33	19	18	13
R2012	Active	16	32	17	10	6
R2013	Active	29	10	25	33	9
R2014	Placebo	10	10	8	13	7
R2015	Active	45	8	18	22	17
R2016	Placebo	6	1	2	2	1
R2017	Active	10	1	6	6	6
R2018	Placebo	19	8	.	9	.
R2019	Placebo	15	8	9	12	8
R2020	Active	11	2	.	.	.
R2021	Active	4	1	2	1	6
R2022	Placebo	17	10	.	.	21
R2023	Placebo	9	3	6	1	.
R2024	Active	7	1	1	.	3
R2025	Active	15	2	2	.	.
R2026	Active	20	9	13	9	33
R2027	Active	21	1	11	11	23
R2028	Placebo	26	7	11	9	26
R2029	Placebo	33	3	11	14	20
R2030	Placebo	11	.	.	9	.
R2031	Placebo	13	1	0	0	5
R2032	Active	6	2	0	.	.
R4001	Placebo	34	11	3	26	.
R4002	Active	22	0	2	1	0
R4003	Placebo	2	0	9	9	16
R4004	Active	24	.	.	23	.
R4005	Active	23	3	6	6	27
R4006	Placebo	26	.	.	16	.
R4007	Active	21	11	12	21	19
R4008	Active	43	0	43	28	36
R4009	Placebo	14	8	11	.	.
R4010	Placebo	20	4	0	6	15
R4011	Placebo	16	2	17	.	17
R4012	Active	23	1	0	4	2
R4013	Active	45	.	.	27	.
R4014	Placebo	29	45	18	25	.
R4015	Placebo	24	0	8	27	26
R4016	Active	20	7	5	6	16
R4017	Active	25	9	5	20	28
R4018	Placebo	52	18	25	20	14
R4019	Placebo	21	1	0	.	18
R4020	Active	21	3	2	2	3
R4021	Placebo	26	10	7	20	.
R4022	Active	11	4	6	.	5
R4023	Placebo	24	1	0	2	11
R4024	Active	17	.	.	14	.

**CONFIDENTIAL**

**Listing 3: Expired Air CO (ppm)**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

**(USA)**

Subject ID	Group	week 0	week 6	week 10	week 16	week 28
R4025	Active	38	.	.	30	.
R4026	Placebo	34	8	15	17	20
R4027	Active	30	2	0	3	10
R4028	Active	32	14	27	26	25
R4029	Placebo	19	5	23	12	14
R4030	Placebo	20	16	.	21	.
R4031	Placebo	16	.	.	15	.
R4032	Placebo	6	7	.	2	3
R4033	Active	34	.	0	2	2
R4034	Active	21	.	.	27	.
R4035	Active	26	20	.	35	20
R4036	Placebo	23	0	5	11	6
R4037	Placebo	18	26	9	10	15
R4038	Placebo	28	29	28	22	30
R4039	Active	37	20	13	27	25
R4040	Active	45	2	3	3	0
R4041	Placebo	37	20	24	22	19
R4042	Active	26	28	34	.	30
R4043	Active	27	.	.	34	.
R4044	Active	15	2	.	20	.
R4045	Placebo	32	3	9	8	14
R4046	Placebo	26	11	.	48	.
R4047	Placebo	44	22	31	34	39
R4048	Active	22	11	.	.	.
R4049	Active	25	9	17	24	28
R4050	Placebo	20	14	8	15	25
R4051	Active	12	3	11	12	4
R4052	Placebo	16	8	10	6	9
R4053	Active	26	.	.	11	.
R4054	Placebo	12	.	15	.	.
R4055	Active	46	3	6	15	12
R4056	Active	23	11	8	15	.
R4057	Active	22	.	25	.	17
R4058	Placebo	19	17	14	24	23
R4059	Placebo	24	.	18	6	2
R4060	Placebo	33	.	17	23	20
R4061	Active	27	.	.	22	.
R4062	Placebo	12	9	6	12	10
R4063	Active	13	.	4	3	3
R4064	Placebo	24	13	18	.	10
R4065	Active	20	10	.	.	.
R4066	Placebo	9	4	.	24	.
R4067	Placebo	28	.	.	21	.
R4068	Active	46	34	38	33	29
R4069	Active	18	11	.	17	8
R4070	Placebo	27	41	37	47	41
R4071	Active	29	0	2	3	2
R4072	Placebo	38	28	42	28	26
R4073	Active	31	.	.	.	.
R4074	Placebo	10	.	.	6	.
R4075	Active	23	12	18	38	.

**CONFIDENTIAL**

**Listing 3: Expired Air CO (ppm)**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

**(USA)**

<b>Subject ID</b>	<b>Group</b>	<b>week 0</b>	<b>week 6</b>	<b>week 10</b>	<b>week 16</b>	<b>week 28</b>
R4076	Placebo	37	.	.	23	.
R4077	Active	29	15	.	25	.
R4078	Placebo	21	23	.	16	.
R4079	Placebo	11	17	17	.	18
R4080	Active	14	.	.	.	.
R4081	Active	8	.	.	18	.
R4082	Placebo	22	.	.	36	.
R4083	Active	15	16	41	37	21
R4084	Placebo	15	27	.	.	.
R4085	Active	17	.	.	.	.
R4086	Active	25	5	.	.	.
R4087	Placebo	19	.	.	19	.
R4088	Placebo	15	34	.	.	.
R4089	Placebo	20	.	17	13	.
R4090	Active	1	0	2	2	0
R4091	Active	11	1	2	0	5
R4092	Active	49	36	35	.	30
R4093	Placebo	28	8	14	10	15
R4094	Placebo	18	5	10	17	5
R4095	Active	31	.	.	.	.
R4096	Placebo	5	7	8	11	12
R4097	Active	.	17	26	20	21
R4098	Placebo	32	.	.	18	.
R4099	Active	23	3	3	3	1
R4100	Active	34	0	2	0	0
R4101	Placebo	18	.	.	.	.
R4102	Placebo	9	.	.	0	16
R4103	Placebo	23	14	.	.	.
R4104	Placebo	34	.	.	.	.
R4105	Active	21	2	0	3	3
R4106	Active	18	13	22	.	.
R4107	Active	30	1	9	.	9
R4108	Placebo	14	.	.	.	.
R4109	Placebo	26	.	.	.	.
R4110	Active	19	.	.	17	.
R4111	Placebo	6	.	.	.	.
R4112	Active	11	.	.	10	.
R4113	Active	25	9	4	.	18
R4114	Placebo	21	2	10	2	1
R4115	Active	24	18	.	.	.
R4116	Placebo	17	2	0	5	0
R4117	Active	33	16	14	17	12
R4118	Placebo	23	4	10	8	4
R4119	Placebo	18	14	25	.	4
R4120	Active	17	3	9	.	14
R4121	Placebo	30	.	.	.	.

**CONFIDENTIAL**

**Listing 4: User Diary**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Subject not smoked cigarettes in past week  
(USA)**

Subject ID	Group	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10
R1001	Active	No	No	No	No	No	No	Yes	Yes	Yes	No
R1002	Placebo	No									
R1003	Active	No	.	.	.	.	.	.	.	.	.
R1004	Placebo	No	No	No	No	No	.	No	Yes	No	No
R1005	Active	No	.	No							
R1006	Placebo	No	No	No	No	No	.	No	No	No	No
R1007	Active	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes
R1008	Placebo	No	.								
R1009	Active	No	.								
R1010	Active	No	No	No	No	Yes	Yes	Yes	Yes	No	Yes
R1011	Placebo	No									
R1012	Placebo	No									
R1013	Placebo	No									
R1014	Placebo	.	.	.	.	.	.	.	.	.	.
R1015	Active	No									
R1016	Active	No	No	No	No	No	No	.	No	No	No
R1017	Active	No									
R1018	Placebo	No									
R1019	Active	No									
R1020	Placebo	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes
R1021	Placebo	No									
R1022	Active	No	No	No	.	No	No	No	No	No	No
R1023	Placebo	No	No	No	No	No	No	.	.	.	.
R1024	Active	No	No	No	No	.	No	No	No	No	No
R1025	Active	No	No	No	Yes						
R1026	Active	No									
R1027	Placebo	No	No	.	.	.	.	.	.	.	.
R1028	Placebo	No									
R1029	Active	No	No	No	No	Yes	.	.	.	.	.
R1030	Placebo	No	No	No	Yes	Yes	Yes	No	No	No	No
R1031	Active	No									
R1032	Active	No	No	No	Yes	Yes	Yes	No	No	No	Yes
R1033	Placebo	No	No	No	No	No	.	.	.	.	.
R1034	Placebo	No									
R1035	Active	No									
R1036	Placebo	No	No	No	Yes	No	Yes	Yes	No	No	Yes
R1037	Active	No									
R5001	Placebo	No									
R5002	Active	No	No	No	Yes	No	Yes	Yes	Yes	Yes	Yes
R5003	Placebo	No									
R5004	Active	No	No	No	No	.	No	No	No	No	No
R5005	Placebo	No	No	No	No	.	.	.	.	.	.
R5006	Active	No	No	.	No						
R5007	Active	.	.	.	.	.	.	.	.	.	.
R5008	Placebo	No	No	No	No	.	No	No	No	No	No
R5009	Placebo	No	No	.	.	.	.	.	.	.	.
R5010	Active	No	No	No	No	No	.	.	.	.	.
R5011	Active	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes
R5012	Placebo	No	No	No	.	.	.	.	.	.	.
R5013	Active	No									

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**Listing 4: User Diary**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Subject not smoked cigarettes in past week  
(USA)**

Subject ID	Group	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10
R5014	Placebo	No									
R5015	Placebo	No	No	No	No	No	.	.	No	No	No
R5016	Placebo	No	No	No	No	No	No	.	.	.	.
R5017	Active	.	.	.	.	.	.	.	.	.	.
R5018	Active	No	No	No	No	No	.	No	No	No	No
R5019	Placebo	No	No	No	No	No	No	.	No	No	No
R5020	Active	No									
R5021	Placebo	No	No	No	No	No	.	Yes	Yes	Yes	No
R5022	Active	No									
R5023	Active	No	.								
R5024	Placebo	.	.	.	.	.	.	.	.	.	.
R5025	Placebo	No									
R5026	Placebo	.	.	.	.	.	.	.	.	.	.
R5027	Active	No	No	No	No	No	Yes	.	Yes	Yes	Yes
R5028	Active	No	No	.	No	Yes	.	Yes	Yes	No	.
R3001	Active	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes
R3002	Placebo	No	No	Yes							
R3003	Active	Yes	No	No	No	No	.	Yes	Yes	No	No
R3004	Placebo	No	No	No	No	No	.	No	No	No	No
R3005	Placebo	No	No	No	No	No	.	No	No	No	No
R3006	Active	No	No	No	No	No	.	No	No	No	No
R3007	Placebo	No	No	No	No	No	Yes	Yes	Yes	No	No
R3008	Placebo	No	Yes	Yes	Yes						
R3009	Active	No	No	No	No	No	Yes	Yes	No	.	.
R3010	Placebo	No	No	No	Yes						
R3011	Active	No	No	No	No	Yes	Yes	Yes	Yes	Yes	.
R3012	Active	No	No	.	.	.	.	.	.	.	.
R3013	Active	No	No	No	No	.	Yes	Yes	Yes	Yes	Yes
R3014	Placebo	No	No	No	No	No	.	No	No	No	No
R3015	Placebo	.	.	.	.	.	.	.	.	.	.
R3016	Active	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No
R3017	Active	No	No	Yes	Yes	.	.	.	.	.	.
R3018	Placebo	No	No	No	No	Yes	Yes	Yes	Yes	Yes	.
R3019	Placebo	No	No	No	No	.	No	No	No	No	No
R3020	Active	No	Yes	.							
R3021	Active	.	.	.	.	.	.	.	.	.	.
R3022	Placebo	No									
R3023	Placebo	No	No	No	No	.	.	.	.	.	.
R3024	Active	No	No	.	.	.	.	.	.	.	.
R3025	Placebo	No	.								
R3026	Active	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes
R3027	Active	No	No	No	No	No	.	No	No	No	.
R3028	Placebo	No	No	No	.	No	No	No	No	No	.
R3029	Placebo	No	No	No	No	No	.	.	.	.	.
R3030	Active	.	.	.	.	.	.	.	.	.	.
R3031	Active	No	No	No	No	.	.	Yes	No	.	.
R3032	Placebo	.	.	.	.	.	.	.	.	.	.
R2001	Active	.	.	.	.	.	.	.	.	.	.
R2002	Active	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	.
R2003	Active	No	No	Yes	No	No	Yes	Yes	Yes	Yes	.

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**Listing 4: User Diary**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Subject not smoked cigarettes in past week  
(USA)**

Subject ID	Group	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10
R2004	Placebo	No	No	No	No	No	.	.	.	.	.
R2005	Placebo	No	No	No	No	No	Yes	Yes	Yes	Yes	.
R2006	Placebo	No	No	No	No	No	.	No	No	No	Yes
R2007	Placebo	No									
R2008	Active	No	No	No	No	No	.	.	.	.	.
R2009	Placebo	No	No	No	No	No	No	Yes	Yes	Yes	Yes
R2010	Active	No									
R2011	Placebo	No	No	No	Yes	No	.	No	No	No	No
R2012	Active	No	No	No	Yes	No	No	No	No	No	No
R2013	Active	No	Yes	No	No	.	Yes	No	No	Yes	No
R2014	Placebo	.	No								
R2015	Active	No	No	No	Yes	.	No	No	No	No	No
R2016	Placebo	No	No	No	No	No	No	Yes	Yes	No	No
R2017	Active	No	No	No	No	No	Yes	Yes	Yes	Yes	No
R2018	Placebo	No									
R2019	Placebo	No									
R2020	Active	No	No	No	Yes	Yes	.	.	.	.	.
R2021	Active	No	No	No	No	No	No	Yes	Yes	Yes	Yes
R2022	Placebo	No									
R2023	Placebo	No	No	No	No	No	No	Yes	Yes	Yes	Yes
R2024	Active	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes
R2025	Active	No	.								
R2026	Active	No									
R2027	Active	No									
R2028	Placebo	No									
R2029	Placebo	No									
R2030	Placebo	Yes	No	No	No	No	No	.	.	.	.
R2031	Placebo	No	No	No	No	No	No	Yes	Yes	Yes	Yes
R2032	Active	No	No	No	No	No	Yes	Yes	Yes	Yes	.
R4001	Placebo	No	No	No	No	No	Yes	Yes	No	Yes	Yes
R4002	Active	No	No	Yes							
R4003	Placebo	Yes	No								
R4004	Active	No	No	No	.	.	.	.	.	.	.
R4005	Active	No									
R4006	Placebo	No	No	No	.	.	.	.	.	.	.
R4007	Active	No									
R4008	Active	No									
R4009	Placebo	.	No	.	No						
R4010	Placebo	No									
R4011	Placebo	No									
R4012	Active	No	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes
R4013	Active	Yes	No	No	No	No	.	.	.	.	.
R4014	Placebo	No									
R4015	Placebo	No									
R4016	Active	No	No	No	No	No	No	Yes	No	Yes	No
R4017	Active	No									
R4018	Placebo	No									
R4019	Placebo	No	No	No	Yes						
R4020	Active	No	No	No	Yes						
R4021	Placebo	No									

**CONFIDENTIAL**

**Listing 4: User Diary**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Subject not smoked cigarettes in past week  
(USA)**

Subject ID	Group	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10
R4022	Active	No									
R4023	Placebo	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes
R4024	Active	No	No	No	No	No	.	.	.	.	.
R4025	Active	No	No	No	No	No	.	.	.	.	.
R4026	Placebo	No	No	No	No	No	.	No	No	No	No
R4027	Active	No	No	No	Yes						
R4028	Active	No									
R4029	Placebo	No	No	No	No	No	Yes	No	Yes	Yes	No
R4030	Placebo	No	.								
R4031	Placebo	No	No	No	.	.	.	.	.	.	.
R4032	Placebo	No									
R4033	Active	No	No	No	Yes						
R4034	Active	No	No	No	.	.	.	.	.	.	.
R4035	Active	No									
R4036	Placebo	No	No	No	No	No	Yes	Yes	No	No	No
R4037	Placebo	No									
R4038	Placebo	No	No	No	No	No	.	No	No	No	No
R4039	Active	No									
R4040	Active	No	No	No	No	No	Yes	No	Yes	Yes	Yes
R4041	Placebo	No									
R4042	Active	No									
R4043	Active	No	No	No	No	.	.	.	.	.	.
R4044	Active	No	.								
R4045	Placebo	No	No	No	No	No	No	Yes	No	No	No
R4046	Placebo	No	No	No	.	No	No	No	No	No	.
R4047	Placebo	No									
R4048	Active	No									
R4049	Active	No									
R4050	Placebo	No									
R4051	Active	No									
R4052	Placebo	No									
R4053	Active	No	.	.							
R4054	Placebo	No									
R4055	Active	No									
R4056	Active	No									
R4057	Active	No									
R4058	Placebo	No									
R4059	Placebo	No	No	No	No	.	.	No	No	No	No
R4060	Placebo	No									
R4061	Active	No	No	No	No	.	.	.	.	.	.
R4062	Placebo	No									
R4063	Active	No									
R4064	Placebo	No									
R4065	Active	No									
R4066	Placebo	No	No	No	No	.	.	.	.	.	.
R4067	Placebo	No	No	No	No	.	.	.	.	.	.
R4068	Active	No									
R4069	Active	No									
R4070	Placebo	No									
R4071	Active	No	No	No	Yes						

**CONFIDENTIAL**

**Listing 4: User Diary**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Subject not smoked cigarettes in past week  
(USA)**

Subject ID	Group	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10
R4072	Placebo	No									
R4073	Active	.	.	.	.	.	.	.	.	.	.
R4074	Placebo	No	No	No	No	No	.	.	.	.	.
R4075	Active	No	No	No	No	Yes	No	Yes	No	No	No
R4076	Placebo	No	.								
R4077	Active	No									
R4078	Placebo	No	.								
R4079	Placebo	No									
R4080	Active	.	.	.	.	.	.	.	.	.	.
R4081	Active	No	No	No	No	No	.	.	.	.	.
R4082	Placebo	No	No	No	No	No	.	.	.	.	.
R4083	Active	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No
R4084	Placebo	No	.								
R4085	Active	.	.	.	.	.	.	.	.	.	.
R4086	Active	No	No	No	No	No	No	.	.	.	.
R4087	Placebo	No									
R4088	Placebo	No	No	No	No	No	.	.	.	.	.
R4089	Placebo	No									
R4090	Active	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes
R4091	Active	No									
R4092	Active	No									
R4093	Placebo	No									
R4094	Placebo	No									
R4095	Active	.	.	.	.	.	.	.	.	.	.
R4096	Placebo	No									
R4097	Active	No									
R4098	Placebo	No	No	No	No	No	.	.	.	.	.
R4099	Active	No	Yes								
R4100	Active	Yes	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes
R4101	Placebo	.	.	.	.	.	.	.	.	.	.
R4102	Placebo	No	No	No	No	No	No	Yes	Yes	Yes	Yes
R4103	Placebo	No	No	No	No	No	.	.	.	.	.
R4104	Placebo	.	.	.	.	.	.	.	.	.	.
R4105	Active	No	Yes								
R4106	Active	No	.								
R4107	Active	No									
R4108	Placebo	No	No	No	No	No	.	.	.	.	.
R4109	Placebo	No	No	No	No	No	.	.	.	.	.
R4110	Active	No	No	No	No	No	.	.	.	.	.
R4111	Placebo	.	.	.	.	.	.	.	.	.	.
R4112	Active	No	No	No	No	No	.	.	.	.	.
R4113	Active	No									
R4114	Placebo	No									
R4115	Active	No	No	No	No	No	.	.	.	.	.
R4116	Placebo	No	No	No	Yes	No	No	No	No	No	Yes
R4117	Active	No	No	No	No	No	Yes	No	No	No	No
R4118	Placebo	No									
R4119	Placebo	No									
R4120	Active	No									
R4121	Placebo	.	.	.	.	.	.	.	.	.	.

**CONFIDENTIAL**

**Listing 4: User Diary**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials

**Subject not smoked cigarettes in past week  
(USA)**

Subject ID	Group	Week 11	Week 12	Week 13	Week 14	Week 15	Week 16	Week 17	Week 18	Week 19	Week 20
R1001	Active	Yes	Yes	Yes	No						
R1002	Placebo	No									
R1003	Active	.	.	.	.	.	.	.	.	.	.
R1004	Placebo	No									
R1005	Active	No	No	Yes	Yes	No	No	Yes	Yes	Yes	Yes
R1006	Placebo	No									
R1007	Active	Yes									
R1008	Placebo	.	.	.	.	.	.	.	.	.	.
R1009	Active	.	.	.	.	.	.	.	.	.	.
R1010	Active	Yes									
R1011	Placebo	No									
R1012	Placebo	No									
R1013	Placebo	No									
R1014	Placebo	.	.	.	.	.	.	.	.	.	.
R1015	Active	No									
R1016	Active	No									
R1017	Active	No									
R1018	Placebo	.	.	.	.	.	.	.	.	.	.
R1019	Active	No									
R1020	Placebo	Yes	No								
R1021	Placebo	No									
R1022	Active	No									
R1023	Placebo	.	.	.	.	.	.	.	.	.	.
R1024	Active	No									
R1025	Active	Yes									
R1026	Active	No	No	No	Yes	No	No	No	No	No	No
R1027	Placebo	.	.	.	.	.	.	.	.	.	.
R1028	Placebo	No									
R1029	Active	.	.	.	.	.	.	.	.	.	.
R1030	Placebo	No									
R1031	Active	No									
R1032	Active	Yes	Yes	Yes	Yes	Yes	Yes	.	.	.	.
R1033	Placebo	.	.	.	.	.	.	.	.	.	.
R1034	Placebo	No									
R1035	Active	No									
R1036	Placebo	.	.	.	.	.	.	.	.	.	.
R1037	Active	No	No	No	Yes	Yes	Yes	No	No	No	No
R5001	Placebo	No									
R5002	Active	Yes	Yes	Yes	Yes	No	No	No	No	No	No
R5003	Placebo	No									
R5004	Active	No									
R5005	Placebo	.	.	.	.	.	.	.	.	.	.
R5006	Active	No									
R5007	Active	.	.	.	.	.	.	.	.	.	.
R5008	Placebo	No									
R5009	Placebo	.	.	.	.	.	.	.	.	.	.
R5010	Active	.	.	.	.	.	.	.	.	.	.
R5011	Active	Yes									
R5012	Placebo	.	.	.	.	.	.	.	.	.	.
R5013	Active	No									

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**Listing 4: User Diary**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Subject not smoked cigarettes in past week  
(USA)**

Subject ID	Group	Week 11	Week 12	Week 13	Week 14	Week 15	Week 16	Week 17	Week 18	Week 19	Week 20
R5014	Placebo	No	.	.	.						
R5015	Placebo	No									
R5016	Placebo	.	.	.	.	.	.	.	.	.	.
R5017	Active	.	.	.	.	.	.	.	.	.	.
R5018	Active	No									
R5019	Placebo	No									
R5020	Active	No									
R5021	Placebo	Yes	Yes	No	Yes	Yes	No	.	.	.	.
R5022	Active	No									
R5023	Active	No									
R5024	Placebo	.	.	.	.	.	.	.	.	.	.
R5025	Placebo	No	.	.							
R5026	Placebo	.	.	.	.	.	.	.	.	.	.
R5027	Active	Yes	Yes	Yes	Yes	Yes	Yes	.	.	.	.
R5028	Active	No	No	No	No	No	No	.	.	.	No
R3001	Active	Yes									
R3002	Placebo	Yes									
R3003	Active	Yes									
R3004	Placebo	No									
R3005	Placebo	No	No	No	No	.	.	.	.	.	.
R3006	Active	No	No	No	No	No	Yes	No	No	No	No
R3007	Placebo	No									
R3008	Placebo	Yes									
R3009	Active	.	.	.	.	.	.	.	.	.	.
R3010	Placebo	Yes									
R3011	Active	.	.	.	.	.	.	Yes	Yes	Yes	Yes
R3012	Active	.	.	.	.	.	.	.	.	.	.
R3013	Active	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes
R3014	Placebo	.	.	.	.	.	.	.	.	.	.
R3015	Placebo	.	.	.	.	.	.	.	.	.	.
R3016	Active	Yes	Yes	Yes	No	Yes	No	No	No	No	No
R3017	Active	.	.	.	.	.	.	.	.	.	.
R3018	Placebo	Yes	No	Yes	No	Yes	Yes	Yes	.	.	.
R3019	Placebo	No									
R3020	Active	.	.	.	.	.	.	Yes	Yes	Yes	Yes
R3021	Active	.	.	.	.	.	.	.	.	.	.
R3022	Placebo	No									
R3023	Placebo	.	.	.	.	.	.	.	.	.	.
R3024	Active	.	.	.	.	.	.	.	.	.	.
R3025	Placebo	.	.	.	.	.	.	.	.	.	.
R3026	Active	Yes									
R3027	Active	.	.	.	.	.	.	.	.	.	.
R3028	Placebo	.	.	.	.	.	.	No	No	No	No
R3029	Placebo	.	.	.	.	.	.	.	.	.	.
R3030	Active	.	.	.	.	.	.	.	.	.	.
R3031	Active	.	.	.	.	.	.	.	.	.	No
R3032	Placebo	.	.	.	.	.	.	.	.	.	.
R2001	Active	.	.	.	.	.	.	.	.	.	.
R2002	Active	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
R2003	Active	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes

**CONFIDENTIAL**

**Listing 4: User Diary**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")

on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Subject not smoked cigarettes in past week  
(USA)**

Subject ID	Group	Week 11	Week 12	Week 13	Week 14	Week 15	Week 16	Week 17	Week 18	Week 19	Week 20
R2004	Placebo	.	.	.	.	.	.	.	.	.	.
R2005	Placebo	Yes									
R2006	Placebo	Yes	No	No	Yes	Yes	No	No	.	.	.
R2007	Placebo	No									
R2008	Active	.	.	.	.	.	.	.	.	.	.
R2009	Placebo	Yes									
R2010	Active	No									
R2011	Placebo	No									
R2012	Active	No									
R2013	Active	.	.	.	.	.	No	Yes	Yes	No	No
R2014	Placebo	No	No	Yes	No						
R2015	Active	No									
R2016	Placebo	Yes	Yes	No	No	Yes	No	No	.	No	No
R2017	Active	No									
R2018	Placebo	.	.	.	.	.	.	No	No	No	No
R2019	Placebo	No									
R2020	Active	.	.	.	.	No	No	No	No	No	No
R2021	Active	Yes	No								
R2022	Placebo	No	No	No	No	No	.	.	.	.	No
R2023	Placebo	Yes									
R2024	Active	Yes	Yes	Yes	Yes	Yes	Yes	.	Yes	Yes	Yes
R2025	Active	.	.	.	.	.	.	.	.	.	.
R2026	Active	No									
R2027	Active	No									
R2028	Placebo	No									
R2029	Placebo	No									
R2030	Placebo	.	.	.	.	.	.	.	.	.	.
R2031	Placebo	Yes									
R2032	Active	.	.	.	.	.	.	.	.	.	.
R4001	Placebo	Yes	Yes	Yes	Yes	Yes	No	.	.	.	.
R4002	Active	Yes	Yes	Yes	Yes	Yes	.	Yes	Yes	Yes	Yes
R4003	Placebo	No									
R4004	Active	.	.	.	.	.	.	.	.	.	.
R4005	Active	Yes	Yes	No	No	.	No	No	No	No	No
R4006	Placebo	.	.	.	.	.	.	.	.	.	.
R4007	Active	No									
R4008	Active	No									
R4009	Placebo	No	No	No	No	No	No	.	.	.	.
R4010	Placebo	No									
R4011	Placebo	No									
R4012	Active	Yes	Yes	Yes	Yes	No	Yes	No	No	No	.
R4013	Active	.	.	.	.	.	.	.	.	.	.
R4014	Placebo	No	No	No	No	No	No	.	.	.	.
R4015	Placebo	No									
R4016	Active	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No
R4017	Active	No									
R4018	Placebo	No									
R4019	Placebo	Yes	Yes	Yes	No						
R4020	Active	Yes									
R4021	Placebo	No	No	No	No	No	No	.	.	.	.

**CONFIDENTIAL**

**Listing 4: User Diary**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Subject not smoked cigarettes in past week  
(USA)**

Subject ID	Group	Week 11	Week 12	Week 13	Week 14	Week 15	Week 16	Week 17	Week 18	Week 19	Week 20
R4022	Active	No	No	No	Yes	No	No	.	.	.	.
R4023	Placebo	Yes									
R4024	Active	.	.	.	.	.	.	.	.	.	.
R4025	Active	.	.	.	.	.	.	.	.	.	.
R4026	Placebo	No									
R4027	Active	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No
R4028	Active	No	No	No	No	No	.	No	No	No	No
R4029	Placebo	Yes									
R4030	Placebo	.	.	.	.	.	.	.	.	.	.
R4031	Placebo	.	.	.	.	.	.	.	.	.	.
R4032	Placebo	No	No	No	Yes	Yes	Yes	Yes	No	No	.
R4033	Active	Yes	Yes	Yes	Yes	Yes	.	Yes	Yes	Yes	Yes
R4034	Active	.	.	.	.	.	.	.	.	.	.
R4035	Active	No	No	No	No	.	.	No	No	No	No
R4036	Placebo	No									
R4037	Placebo	No									
R4038	Placebo	No	No	No	.	No	No	No	No	No	No
R4039	Active	No									
R4040	Active	Yes									
R4041	Placebo	No									
R4042	Active	No									
R4043	Active	.	.	.	.	.	.	.	.	.	.
R4044	Active	.	.	.	.	.	.	.	.	.	.
R4045	Placebo	No									
R4046	Placebo	.	.	.	.	.	.	.	.	.	.
R4047	Placebo	No									
R4048	Active	No	.	.	.	.	.	.	.	.	.
R4049	Active	No									
R4050	Placebo	No									
R4051	Active	No									
R4052	Placebo	No									
R4053	Active	.	.	.	.	.	.	.	.	.	.
R4054	Placebo	No									
R4055	Active	No									
R4056	Active	No	No	No	No	No	.	.	.	.	.
R4057	Active	No									
R4058	Placebo	No									
R4059	Placebo	No	Yes	Yes	Yes						
R4060	Placebo	No									
R4061	Active	.	.	.	.	.	.	.	.	.	.
R4062	Placebo	No									
R4063	Active	No	No	No	No	No	Yes	No	No	No	No
R4064	Placebo	No	No	No	No	No	No	.	.	.	.
R4065	Active	No									
R4066	Placebo	.	.	.	.	.	.	.	.	.	.
R4067	Placebo	.	.	.	.	.	.	.	.	.	.
R4068	Active	No	No	No	No	.	No	Yes	No	No	No
R4069	Active	No									
R4070	Placebo	No									
R4071	Active	Yes									

**CONFIDENTIAL**

**Listing 4: User Diary**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Subject not smoked cigarettes in past week  
(USA)**

<b>Subject ID</b>	<b>Group</b>	<b>Week 11</b>	<b>Week 12</b>	<b>Week 13</b>	<b>Week 14</b>	<b>Week 15</b>	<b>Week 16</b>	<b>Week 17</b>	<b>Week 18</b>	<b>Week 19</b>	<b>Week 20</b>
R4072	Placebo	No									
R4073	Active	.	.	.	.	.	.	.	.	.	.
R4074	Placebo	.	.	.	.	.	.	.	.	.	.
R4075	Active	Yes	Yes	Yes	Yes	No	No	.	.	.	.
R4076	Placebo	.	.	.	.	.	.	.	.	.	.
R4077	Active	No	No	No	No	No	No	.	.	.	.
R4078	Placebo	.	.	.	.	.	.	.	.	.	.
R4079	Placebo	No									
R4080	Active	.	.	.	.	.	.	.	.	.	.
R4081	Active	.	.	.	.	.	.	.	.	.	.
R4082	Placebo	.	.	.	.	.	.	.	.	.	.
R4083	Active	No									
R4084	Placebo	.	.	.	.	.	.	.	.	.	.
R4085	Active	.	.	.	.	.	.	.	.	.	.
R4086	Active	.	.	.	.	.	.	.	.	.	.
R4087	Placebo	No	No	No	.	.	.	.	.	.	.
R4088	Placebo	.	.	.	.	.	.	.	.	.	.
R4089	Placebo	No	No	No	No	No	No	.	.	.	.
R4090	Active	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
R4091	Active	No	No	No	No	No	Yes	.	.	.	.
R4092	Active	No									
R4093	Placebo	No									
R4094	Placebo	No									
R4095	Active	.	.	.	.	.	.	.	.	.	.
R4096	Placebo	No									
R4097	Active	No									
R4098	Placebo	.	.	.	.	.	.	.	.	.	.
R4099	Active	Yes	Yes	Yes	.	Yes	Yes	Yes	Yes	No	Yes
R4100	Active	Yes									
R4101	Placebo	.	.	.	.	.	.	.	.	.	.
R4102	Placebo	Yes									
R4103	Placebo	.	.	.	.	.	.	.	.	.	.
R4104	Placebo	.	.	.	.	.	.	.	.	.	.
R4105	Active	Yes									
R4106	Active	.	.	.	.	.	.	.	.	.	.
R4107	Active	No									
R4108	Placebo	.	.	.	.	.	.	.	.	.	.
R4109	Placebo	.	.	.	.	.	.	.	.	.	.
R4110	Active	.	.	.	.	.	.	.	.	.	.
R4111	Placebo	.	.	.	.	.	.	.	.	.	.
R4112	Active	.	.	.	.	.	.	.	.	.	.
R4113	Active	No									
R4114	Placebo	No									
R4115	Active	.	.	.	.	.	.	.	.	.	.
R4116	Placebo	No	No	No	No	Yes	No	No	No	No	No
R4117	Active	Yes	Yes	No							
R4118	Placebo	No									
R4119	Placebo	No									
R4120	Active	No	No	No	No	No	No	.	.	.	.
R4121	Placebo	.	.	.	.	.	.	.	.	.	.

**CONFIDENTIAL**

**Listing 4: User Diary**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Subject not smoked cigarettes in past week  
(USA)**

Subject ID	Group	Week 21	Week 22	Week 23	Week 24	Week 25	Week 26	Week 27	Week 28
R1001	Active	No	No	Yes	Yes	No	No	No	No
R1002	Placebo	No							
R1003	Active	.	.	.	.	.	.	.	.
R1004	Placebo	No	No	Yes	No	Yes	Yes	No	No
R1005	Active	Yes	Yes	Yes	Yes	Yes	No	No	.
R1006	Placebo	No							
R1007	Active	Yes							
R1008	Placebo	.	.	.	.	.	.	.	.
R1009	Active	.	.	.	.	.	.	.	.
R1010	Active	Yes							
R1011	Placebo	No							
R1012	Placebo	No							
R1013	Placebo	No							
R1014	Placebo	.	.	.	.	.	.	.	.
R1015	Active	No							
R1016	Active	No							
R1017	Active	No							
R1018	Placebo	.	.	.	.	.	.	.	.
R1019	Active	No							
R1020	Placebo	No	Yes	No	No	No	Yes	.	.
R1021	Placebo	No							
R1022	Active	No							
R1023	Placebo	.	.	.	.	.	.	.	.
R1024	Active	No							
R1025	Active	Yes							
R1026	Active	Yes	Yes	No	No	No	No	No	No
R1027	Placebo	.	.	.	.	.	.	.	.
R1028	Placebo	No							
R1029	Active	.	.	.	.	.	.	.	.
R1030	Placebo	No							
R1031	Active	No	No	No	No	No	Yes	Yes	Yes
R1032	Active	.	.	.	.	.	.	.	.
R1033	Placebo	.	.	.	.	.	.	.	.
R1034	Placebo	No	No	No	No	No	No	.	No
R1035	Active	No							
R1036	Placebo	.	.	.	.	.	.	.	.
R1037	Active	No	Yes						
R5001	Placebo	No							
R5002	Active	No							
R5003	Placebo	No							
R5004	Active	No							
R5005	Placebo	.	.	.	.	.	.	.	.
R5006	Active	No							
R5007	Active	.	.	.	.	.	.	.	.
R5008	Placebo	No							
R5009	Placebo	.	.	.	.	.	.	.	.
R5010	Active	.	.	.	.	.	.	.	.
R5011	Active	Yes							
R5012	Placebo	.	.	.	.	.	.	.	.
R5013	Active	No							

**CONFIDENTIAL**

**Listing 4: User Diary**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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**Subject not smoked cigarettes in past week  
(USA)**

Subject ID	Group	Week 21	Week 22	Week 23	Week 24	Week 25	Week 26	Week 27	Week 28
R5014	Placebo	.	.	.	.	.	.	.	.
R5015	Placebo	No							
R5016	Placebo	.	.	.	.	.	.	.	.
R5017	Active	.	.	.	.	.	.	.	.
R5018	Active	No							
R5019	Placebo	No							
R5020	Active	No							
R5021	Placebo	.	.	.	.	.	.	.	.
R5022	Active	No							
R5023	Active	No							
R5024	Placebo	.	.	.	.	.	.	.	.
R5025	Placebo	.	.	.	.	.	.	.	No
R5026	Placebo	.	.	.	.	.	.	.	.
R5027	Active	.	.	.	.	.	.	.	.
R5028	Active	No							
R3001	Active	Yes							
R3002	Placebo	Yes							
R3003	Active	.	.	.	.	.	.	.	.
R3004	Placebo	No							
R3005	Placebo	.	.	.	.	.	.	.	.
R3006	Active	No	No	No	No	Yes	No	No	No
R3007	Placebo	No							
R3008	Placebo	Yes							
R3009	Active	.	.	.	.	.	.	.	.
R3010	Placebo	Yes							
R3011	Active	Yes	No						
R3012	Active	.	.	.	.	.	.	.	.
R3013	Active	Yes	No	Yes	Yes	Yes	Yes	Yes	No
R3014	Placebo	.	.	.	.	.	.	.	.
R3015	Placebo	.	.	.	.	.	.	.	.
R3016	Active	No							
R3017	Active	.	.	.	.	.	.	.	.
R3018	Placebo	.	.	.	.	.	.	.	.
R3019	Placebo	No	No	No	No	Yes	No	No	No
R3020	Active	Yes							
R3021	Active	.	.	.	.	.	.	.	.
R3022	Placebo	No							
R3023	Placebo	.	.	.	.	.	.	.	.
R3024	Active	.	.	.	.	.	.	.	.
R3025	Placebo	.	.	.	.	.	.	.	.
R3026	Active	Yes							
R3027	Active	.	.	.	.	.	.	.	.
R3028	Placebo	No							
R3029	Placebo	.	.	.	.	.	.	.	.
R3030	Active	.	.	.	.	.	.	.	.
R3031	Active	Yes	Yes	No	No	No	No	No	No
R3032	Placebo	.	.	.	.	.	.	.	.
R2001	Active	.	.	.	.	.	.	.	.
R2002	Active	Yes							
R2003	Active	Yes							

**CONFIDENTIAL**

**Listing 4: User Diary**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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**Subject not smoked cigarettes in past week  
(USA)**

Subject ID	Group	Week 21	Week 22	Week 23	Week 24	Week 25	Week 26	Week 27	Week 28
R2004	Placebo	.	.	.	.	.	.	.	.
R2005	Placebo	Yes							
R2006	Placebo	.	.	.	.	.	.	.	.
R2007	Placebo	No	No	No	No	No	Yes	Yes	No
R2008	Active	.	.	.	.	.	.	.	.
R2009	Placebo	Yes							
R2010	Active	No							
R2011	Placebo	No							
R2012	Active	No							
R2013	Active	No	No	No	Yes	Yes	Yes	No	No
R2014	Placebo	No							
R2015	Active	No							
R2016	Placebo	No							
R2017	Active	No							
R2018	Placebo	.	.	.	.	.	.	.	.
R2019	Placebo	No							
R2020	Active	.	.	.	.	.	.	.	.
R2021	Active	No	.						
R2022	Placebo	No							
R2023	Placebo	Yes							
R2024	Active	Yes	Yes	Yes	Yes	No	No	No	No
R2025	Active	.	.	.	.	.	.	.	.
R2026	Active	No							
R2027	Active	No							
R2028	Placebo	No							
R2029	Placebo	No							
R2030	Placebo	.	.	.	.	.	.	.	.
R2031	Placebo	Yes							
R2032	Active	.	.	.	.	.	.	.	.
R4001	Placebo	.	.	.	.	.	.	.	.
R4002	Active	Yes							
R4003	Placebo	No							
R4004	Active	.	.	.	.	.	.	.	.
R4005	Active	No							
R4006	Placebo	.	.	.	.	.	.	.	.
R4007	Active	No							
R4008	Active	No							
R4009	Placebo	.	.	.	.	.	.	.	.
R4010	Placebo	No							
R4011	Placebo	No	.						
R4012	Active	No							
R4013	Active	.	.	.	.	.	.	.	.
R4014	Placebo	.	.	.	.	.	.	.	.
R4015	Placebo	No							
R4016	Active	No							
R4017	Active	No							
R4018	Placebo	No							
R4019	Placebo	No							
R4020	Active	Yes	No						
R4021	Placebo	.	.	.	.	.	.	.	.

**CONFIDENTIAL**

**Listing 4: User Diary**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Subject not smoked cigarettes in past week  
(USA)**

Subject ID	Group	Week 21	Week 22	Week 23	Week 24	Week 25	Week 26	Week 27	Week 28
R4022	Active	.	.	.	.	.	.	.	.
R4023	Placebo	Yes							
R4024	Active	.	.	.	.	.	.	.	.
R4025	Active	.	.	.	.	.	.	.	.
R4026	Placebo	No							
R4027	Active	No							
R4028	Active	No							
R4029	Placebo	Yes							
R4030	Placebo	.	.	.	.	.	.	.	.
R4031	Placebo	.	.	.	.	.	.	.	.
R4032	Placebo	No							
R4033	Active	Yes							
R4034	Active	.	.	.	.	.	.	.	.
R4035	Active	No							
R4036	Placebo	No	Yes						
R4037	Placebo	No							
R4038	Placebo	No							
R4039	Active	No							
R4040	Active	Yes							
R4041	Placebo	No							
R4042	Active	.	.	.	.	.	.	.	.
R4043	Active	.	.	.	.	.	.	.	.
R4044	Active	.	.	.	.	.	.	.	.
R4045	Placebo	No							
R4046	Placebo	.	.	.	.	.	.	.	.
R4047	Placebo	No							
R4048	Active	.	.	.	.	.	.	.	.
R4049	Active	No							
R4050	Placebo	No	No	No	No	No	.	.	.
R4051	Active	No							
R4052	Placebo	No							
R4053	Active	.	.	.	.	.	.	.	.
R4054	Placebo	No							
R4055	Active	No							
R4056	Active	.	.	.	.	.	.	.	.
R4057	Active	No							
R4058	Placebo	No							
R4059	Placebo	Yes							
R4060	Placebo	No							
R4061	Active	.	.	.	.	.	.	.	.
R4062	Placebo	No							
R4063	Active	No							
R4064	Placebo	.	.	.	.	.	.	.	.
R4065	Active	Yes	Yes	No	No	Yes	Yes	Yes	Yes
R4066	Placebo	.	.	.	.	.	.	.	.
R4067	Placebo	.	.	.	.	.	.	.	.
R4068	Active	No							
R4069	Active	No							
R4070	Placebo	No							
R4071	Active	Yes							

**CONFIDENTIAL**

**Listing 4: User Diary**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

**Subject not smoked cigarettes in past week  
(USA)**

Subject ID	Group	Week 21	Week 22	Week 23	Week 24	Week 25	Week 26	Week 27	Week 28
R4072	Placebo	No							
R4073	Active	.	.	.	.	.	.	.	.
R4074	Placebo	.	.	.	.	.	.	.	.
R4075	Active	.	.	.	.	.	.	.	.
R4076	Placebo	.	.	.	.	.	.	.	.
R4077	Active	.	.	.	.	.	.	.	.
R4078	Placebo	.	.	.	.	.	.	.	.
R4079	Placebo	No							
R4080	Active	.	.	.	.	.	.	.	.
R4081	Active	.	.	.	.	.	.	.	.
R4082	Placebo	.	.	.	.	.	.	.	.
R4083	Active	No							
R4084	Placebo	.	.	.	.	.	.	.	.
R4085	Active	.	.	.	.	.	.	.	.
R4086	Active	.	.	.	.	.	.	.	.
R4087	Placebo	.	.	.	.	.	.	.	.
R4088	Placebo	.	.	.	.	.	.	.	.
R4089	Placebo	.	.	.	.	.	.	.	.
R4090	Active	Yes							
R4091	Active	.	.	.	.	.	.	.	.
R4092	Active	No							
R4093	Placebo	No							
R4094	Placebo	No							
R4095	Active	.	.	.	.	.	.	.	.
R4096	Placebo	No							
R4097	Active	No							
R4098	Placebo	.	.	.	.	.	.	.	.
R4099	Active	No	Yes						
R4100	Active	Yes							
R4101	Placebo	.	.	.	.	.	.	.	.
R4102	Placebo	Yes							
R4103	Placebo	.	.	.	.	.	.	.	.
R4104	Placebo	.	.	.	.	.	.	.	.
R4105	Active	Yes							
R4106	Active	.	.	.	.	.	.	.	.
R4107	Active	No							
R4108	Placebo	.	.	.	.	.	.	.	.
R4109	Placebo	.	.	.	.	.	.	.	.
R4110	Active	.	.	.	.	.	.	.	.
R4111	Placebo	.	.	.	.	.	.	.	.
R4112	Active	.	.	.	.	.	.	.	.
R4113	Active	No							
R4114	Placebo	No	No	No	Yes	Yes	No	Yes	Yes
R4115	Active	.	.	.	.	.	.	.	.
R4116	Placebo	No	No	No	.	No	No	Yes	Yes
R4117	Active	No							
R4118	Placebo	No							
R4119	Placebo	No	No	No	No	No	.	No	No
R4120	Active	.	.	.	.	.	.	.	.
R4121	Placebo	.	.	.	.	.	.	.	.

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**Listing 5: Self Reported Smoking**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

Subject ID	Group	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10
1001	Placebo	30	38	38	37	36	35	30	30	28	29
1002	Placebo	25	26	22	20	27	23	24	24	24	22
1003	Active	10	10	20	20	20	20	20	20	20	20
1004	Active	6	5	6	6	7	7	7	7	7	7
1005	Active	10	10	20	20	10	10	10	12	10	10
1006	Placebo	15	15	15	15	20	15	15	15	15	15
1007	Active	.	.	.	.	.	.	.	.	.	.
1008	Active	30	15	30	15	25	20	30	30	30	30
1009	Placebo	20	15	15	15	17	18	18	17	18	17
1010	Placebo	20	18	16	20	20	22	20	20	20	20
1011	Active	50	50	40	50	50	50	40	50	50	50
1012	Placebo	20	20	15	18	18	18	20	25	25	20
1013	Active	15	15	20	10	15	15	20	20	15	15
1014	Active	25	25	25	20	0	10	30	30	30	25
1015	Active	20	20	25	25	20	20	25	25	25	25
1016	Placebo	25	20	25	22	20	30	25	22	20	28
1017	Placebo	25	22	22	22	25	25	22	25	22	22
1018	Placebo	.	.	.	.	.	.	.	.	.	.
1019	Active	12	12	12	14	14	14	14	14	14	16
1020	Placebo	20	17	18	20	20	20	25	25	25	25
1021	Active	15	12	15	15	10	10	10	12	12	10
1022	Placebo	.	.	.	.	.	.	.	.	.	.
1023	Active	20	16	11	8	8	8	6	5	5	5
1024	Placebo	22	22	25	25	25	25	25	25	25	.
1025	Placebo	3	3	3	6	7	8	5	4	4	8
1026	Placebo	.	.	.	.	.	.	.	.	.	.
1027	Placebo	10	10	15	15	15	20	20	20	20	20
1028	Active	10	15	15	15	20	15	20	20	20	20
1029	Active	23	23	20	20	20	20	20	20	15	15
1030	Active	14	14	14	12	10	10	10	10	10	10
1031	Active	19	19	23	21	20	20	23	21	21	23
1032	Active	.	.	.	.	.	.	.	.	.	.
1033	Placebo	6	6	5	5	5	5	5	7	7	7
1034	Active	.	.	.	.	.	.	.	.	.	.
1035	Placebo	15	14	15	12	15	14	16	12	12	11
1036	Placebo	.	.	.	.	.	.	.	.	.	.
1037	Placebo	6	6	4	6	8	10	8	8	10	9
1038	Active	5	7	8	10	9	10	8	9	10	9
1039	Placebo	12	20	25	25	25	25	.	.	.	.
1040	Active	20	25	30	30	30	30	.	.	.	.
1041	Placebo	10	10	15	15	15	15	15	15	15	15
1042	Active	25	20	20	15	20	20	20	20	20	10
1043	Placebo	12	15	11	10	10	10	10	10	11	10
1044	Active	37	28	27	25	30	30	20	19	40	.
1045	Active	.	.	.	.	.	.	.	.	.	.
1046	Placebo	12	13	15	15	20	20	10	10	10	10
1047	Active	30	30	30	25	25	25	25	25	25	15
1048	Placebo	30	30	30	30	35	35	35	35	35	35
1049	Placebo	20	20	30	30	30	30	30	30	30	32
1050	Active	15	15	15	13	12	10	10	10	10	12

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**Listing 5: Self Reported Smoking**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

<b>Subject ID</b>	<b>Group</b>	<b>Week 1</b>	<b>Week 2</b>	<b>Week 3</b>	<b>Week 4</b>	<b>Week 5</b>	<b>Week 6</b>	<b>Week 7</b>	<b>Week 8</b>	<b>Week 9</b>	<b>Week 10</b>
1205	Placebo	15	15	12	10	15	15	15	17	17	16
1206	Placebo	40	35	25	25	25	25	25	25	25	.
1207	Active	15	15	17	15	14	12	10	10	10	.
1208	Active	15	15	20	20	20	15	15	15	15	15
1209	Active	6	8	7	7	7	6	7	7	7	3
1210	Placebo	20	25	20	20	20	20	20	20	20	15
1211	Active	40	40	40	40	40	40	30	25	25	25
1212	Active	8	8	7	7	7	7	7	7	7	5
1213	Placebo	20	20	20	20	20	20	20	15	15	15
1214	Placebo	15	15	15	15	15	15	15	15	15	15
1215	Active	15	10	12	14	12	15	15	15	15	13
1216	Placebo	10	10	10	6	6	6	6	7	7	10
1217	Active	15	15	15	15	15	15	15	15	15	15
1218	Active	35	40	35	30	30	30	30	30	30	.
1219	Active	10	10	10	10	10	10	15	10	10	.
1220	Placebo	12	18	17	15	17	15	15	15	15	12
1221	Placebo	20	20	20	20	18	20	18	18	17	17
1222	Placebo	20	20	15	15	15	15	20	20	20	20
1223	Active	19	17	18	17	18	17	15	15	18	15
1224	Placebo	28	28	28	25	25	25	25	25	20	15
1225	Active	20	20	30	30	30	25	20	20	20	20
1226	Placebo	15	15	15	15	15	15	12	12	12	15
1227	Active	12	9	12	15	12	13	10	10	10	10
1228	Placebo	10	10	10	10	10	10	6	6	4	4
1229	Placebo	15	15	18	17	18	20	20	20	20	20
1230	Placebo	17	18	17	19	18	19	15	10	11	15
1231	Placebo	16	16	12	10	13	14	14	15	14	12
1232	Active	10	10	10	10	10	10	8	10	9	.
1233	Active	10	10	10	10	10	10	10	10	10	10
1234	Active	30	30	30	30	30	30	25	23	23	30
1235	Active	15	15	7	7	8	7	5	6	6	5
1236	Active	25	25	22	20	20	20	18	13	13	.
1237	Placebo	12	14	14	16	15	15	15	15	13	16
1238	Active	10	10	10	9	9	9	8	8	8	14
1239	Placebo	25	15	17	15	15	15	13	13	14	15
1240	Placebo	13	15	10	10	12	10	10	10	10	10
1241	Placebo	6	11	11	15	15	20	15	20	20	.
1242	Active	6	5	8	8	8	8	10	8	7	10
1243	Placebo	8	7	9	7	7	8	8	7	7	10
1244	Active	10	10	10	18	20	20	20	15	18	12
1245	Placebo	5	10	5	10	8	10	10	10	8	7
1246	Active	8	10	10	15	15	20	20	20	18	20
1247	Placebo	20	20	15	18	15	17	18	15	15	15
1325	Placebo	10	10	10	9	9	9	9	8	7	7
1326	Placebo	20	20	20	18	18	18	17	17	16	16
1327	Active	30	27	27	25	25	25	25	22	24	23
1328	Active	30	30	29	29	28	27	29	27	25	25
1329	Active	20	20	19	19	20	17	17	15	18	16
1330	Placebo	20	20	20	19	19	17	17	20	18	16
1331	Active	20	18	18	19	19	18	17	16	16	16

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**Listing 5: Self Reported Smoking**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

<b>Subject ID</b>	<b>Group</b>	<b>Week 1</b>	<b>Week 2</b>	<b>Week 3</b>	<b>Week 4</b>	<b>Week 5</b>	<b>Week 6</b>	<b>Week 7</b>	<b>Week 8</b>	<b>Week 9</b>	<b>Week 10</b>
1332	Active	30	27	27	26	26	23	23	23	23	22
1333	Placebo	20	20	18	19	18	18	16	17	16	15
1334	Placebo	40	40	35	35	35	35	35	35	35	33
1335	Active	30	30	29	28	26	26	22	22	23	23
1336	Placebo	20	18	18	18	20	17	16	17	15	15
1337	Active	6	6	10	8	12	10	12	13	10	6
1338	Active	25	25	25	22	22	22	20	20	21	20
1339	Active	25	25	20	22	24	22	22	20	20	20
1340	Placebo	40	40	37	37	36	34	34	32	31	30
1341	Placebo	25	23	21	21	21	20	20	20	20	18
1342	Placebo	16	16	18	19	15	15	14	14	15	14
1343	Active	18	18	19	18	18	17	17	17	16	14
1344	Placebo	20	20	19	20	18	18	18	16	15	15
1345	Active	15	15	14	13	13	13	12	12	10	10
1346	Placebo	20	20	20	18	18	18	17	17	15	15
1347	Active	25	25	25	25	25	22	22	20	20	20
1348	Placebo	20	20	20	20	20	20	10	10	10	10
1349	Placebo	30	25	20	20	15	10	15	20	18	17
2001	Placebo	10	8	10	10	10	14	15	15	15	10
2002	Placebo	25	35	35	30	30	30	35	35	35	20
2003	Active	12	12	10	10	10	10	10	10	10	10
2004	Active	20	20	20	25	25	25	25	25	30	30
2005	Active	20	20	20	18	18	18	15	15	15	10
2006	Placebo	12	12	13	14	14	14	15	15	15	15
2007	Active	15	15	12	10	10	9	9	9	10	9
2008	Active	15	15	15	15	15	15	15	15	15	15
2009	Placebo	20	20	18	15	15	15	15	15	15	15
2010	Placebo	40	20	20	20	20	20	18	18	18	18
2011	Active	20	20	15	15	15	15	15	15	15	15
2012	Placebo	30	30	26	30	25	25	20	20	20	20
2013	Active	18	18	20	25	25	30	30	30	30	25
2014	Active	15	15	15	15	14	12	12	10	10	10
2015	Active	7	7	8	8	12	15	15	15	15	15
2016	Placebo	20	20	20	20	20	20	15	17	15	15
2017	Placebo	10	10	15	10	15	15	10	10	10	20
2018	Placebo	12	12	11	10	10	10	10	10	10	12
2019	Active	11	20	15	10	13	15	17	18	18	25
2020	Placebo	20	20	20	18	18	18	15	15	15	12
2021	Active	27	25	25	25	20	20	20	20	20	20
2022	Placebo	40	40	35	36	30	30	25	25	20	20
2023	Active	30	20	20	15	15	15	15	15	15	15
2024	Placebo	30	30	27	25	25	25	20	20	20	20
2025	Placebo	20	20	18	18	15	15	15	15	15	15
2026	Placebo	7	12	13	15	13	14	12	12	14	13
2027	Placebo	10	10	10	10	10	10	10	10	10	10
2028	Active	20	15	15	20	20	15	15	18	15	12
2029	Active	20	20	15	20	14	18	20	20	20	15
2030	Active	20	23	20	23	20	18	18	22	22	18
2031	Active	15	15	12	15	15	12	10	10	10	10
2032	Active	30	30	30	25	25	25	20	20	20	20

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**Listing 5: Self Reported Smoking**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

<b>Subject ID</b>	<b>Group</b>	<b>Week 1</b>	<b>Week 2</b>	<b>Week 3</b>	<b>Week 4</b>	<b>Week 5</b>	<b>Week 6</b>	<b>Week 7</b>	<b>Week 8</b>	<b>Week 9</b>	<b>Week 10</b>
2033	Placebo	10	15	15	15	15	15	15	15	15	15
2034	Active	10	10	15	10	10	15	15	10	10	10
2035	Placebo	.	.	30	25	35	30	25	30	30	30
2036	Placebo	25	25	25	22	22	22	22	22	20	20
2037	Placebo	25	25	25	22	22	20	20	20	25	25
2038	Active	25	25	25	20	20	20	20	20	18	18
2039	Placebo	15	15	15	20	20	18	18	18	18	18
2040	Active	20	20	18	18	15	15	15	15	15	15
2041	Placebo	25	25	22	22	20	20	18	20	18	18
2042	Active	10	10	9	10	10	10	8	8	7	8
2043	Placebo	15	15	12	14	12	10	15	20	20	15
2044	Active	20	21	25	25	20	21	20	18	20	19
2045	Active	30	30	27	28	25	25	24	20	20	20
2046	Placebo	10	10	6	8	12	12	10	12	10	12
2047	Active	20	20	20	20	20	18	18	20	20	18
2048	Placebo	30	40	30	30	25	24	20	18	15	12
2049	Placebo	7	7	6	2	5	5	3	4	4	3
2050	Active	20	20	20	20	20	18	18	20	20	18
2205	Active	30	30	25	25	25	25	25	24	24	24
2206	Placebo	20	20	20	18	17	17	17	16	16	16
2207	Placebo	25	25	25	25	25	23	22	20	20	20
2208	Active	25	25	25	25	23	23	22	22	22	20
2209	Active	20	20	20	20	20	20	18	18	18	16
2210	Placebo	15	15	15	15	15	15	12	12	12	12
2211	Placebo	20	5	10	10	15	20	20	20	20	20
2212	Placebo	30	30	28	28	28	25	25	24	24	20
2213	Active	10	12	15	15	15	15	15	15	15	15
2214	Active	25	25	25	25	25	25	24	24	24	20
2215	Active	30	30	30	30	28	28	28	25	25	25
2216	Placebo	40	40	40	38	38	35	32	32	30	30
2217	Active	30	30	30	28	30	27	27	25	25	25
2218	Placebo	20	20	20	20	20	19	18	18	18	16
2219	Active	20	20	20	20	18	18	18	18	16	16
2220	Placebo	23	20	20	19	16	19	20	20	22	23
2221	Placebo	25	25	24	24	20	20	18	18	18	18
2222	Active	15	15	15	14	14	13	12	12	12	12
2223	Placebo	10	10	10	10	10	9	9	10	10	9
2224	Placebo	20	19	20	19	19	18	20	19	18	20
2225	Placebo	15	13	12	14	10	10	10	11	10	10
2226	Active	40	30	20	20	20	20	20	20	20	20
2227	Active	10	10	10	10	8	9	15	15	10	10
2228	Active	20	20	20	20	18	18	18	18	18	18
2229	Placebo	25	25	20	20	20	20	20	18	18	18
2230	Active	20	20	20	18	18	18	16	16	16	16
2231	Active	8	6	10	12	12	8	8	10	8	8
2232	Placebo	20	20	18	18	18	18	18	16	16	15
2233	Placebo	40	40	38	38	35	35	33	33	32	30
2234	Active	60	58	58	55	55	55	55	53	53	50
2235	Placebo	29	27	25	27	24	27	26	23	25	24
2236	Placebo	15	15	14	14	14	13	13	13	12	12

**CONFIDENTIAL**

**Listing 5: Self Reported Smoking**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

<b>Subject ID</b>	<b>Group</b>	<b>Week 1</b>	<b>Week 2</b>	<b>Week 3</b>	<b>Week 4</b>	<b>Week 5</b>	<b>Week 6</b>	<b>Week 7</b>	<b>Week 8</b>	<b>Week 9</b>	<b>Week 10</b>
2237	Placebo	20	20	20	19	19	18	18	18	18	16
2238	Active	10	10	10	10	10	8	8	8	8	10
2239	Active	20	15	15	25	20	20	15	20	20	15
2240	Active	20	20	20	20	15	15	15	20	17	20
2241	Active	35	35	30	30	30	25	20	25	25	15
2242	Active	15	15	12	10	10	9	10	9	10	10
2243	Placebo	15	15	15	10	10	10	15	20	15	15
2244	Placebo	10	10	10	10	8	8	10	10	10	10
2245	Active	15	15	13	13	14	14	12	12	12	12
2246	Placebo	15	15	15	20	15	15	15	15	15	15
2247	Active	10	10	10	10	10	10	10	10	10	8
2248	Active	20	20	18	18	17	17	17	17	17	15
2249	Placebo	25	25	25	25	20	20	20	20	18	20
2250	Placebo	10	10	10	10	10	10	10	10	10	10
2251	Active	10	10	10	10	10	10	10	10	10	15
2252	Placebo	30	30	27	27	28	27	27	25	25	24
2253	Active	15	17	15	17	15	13	15	15	13	15
2254	Placebo	20	25	25	25	20	20	15	10	10	15
2255	Active	15	15	20	20	20	25	25	20	20	20
2256	Placebo	18	17	17	16	16	15	16	18	19	18
2257	Active	20	20	20	20	20	20	20	20	20	20
2258	Placebo	10	15	10	12	15	17	12	10	10	8
2259	Placebo	20	20	20	18	18	18	16	17	16	16
2260	Placebo	20	20	18	18	18	18	16	17	16	16
2261	Active	15	16	15	15	14	14	13	13	12	12
2262	Active	10	9	9	8	8	10	8	10	9	10
2263	Placebo	20	27	20	30	29	29	27	27	25	25
2264	Active	14	10	10	20	16	15	12	11	10	11
2265	Active	45	45	45	40	40	40	36	36	35	35
2266	Active	15	15	15	15	15	15	15	15	15	15
2267	Active	40	40	38	38	36	36	36	36	36	35
2268	Placebo	15	15	12	15	15	14	15	12	12	15
2269	Placebo	20	20	18	18	16	15	14	12	12	12
2270	Placebo	15	5	13	15	10	10	15	10	10	10
2271	Placebo	10	10	8	8	10	11	10	12	9	10
2272	Placebo	40	40	35	35	32	35	35	35	35	40
2273	Active	25	35	35	35	30	30	30	30	30	30
2274	Placebo	14	14	11	12	11	12	10	10	10	11
2275	Active	15	14	12	12	10	10	13	12	10	10
2276	Active	20	20	20	18	15	15	15	20	20	20
2277	Active	10	6	6	6	8	5	5	4	4	3
2278	Active	10	10	10	10	10	10	10	10	10	10
2279	Placebo	30	30	30	30	30	30	30	30	30	30
2280	Placebo	10	10	9	9	7	7	5	4	5	6
2281	Active	15	10	10	10	10	10	10	10	10	10
2282	Placebo	20	20	18	15	15	15	15	15	15	14
2283	Placebo	35	35	30	30	27	27	25	25	25	27
2284	Active	40	30	30	30	40	40	40	40	40	40
2285	Active	5	7	5	5	3	5	5	5	5	10
2286	Placebo	15	15	17	15	15	15	10	10	11	11

**CONFIDENTIAL**

**Listing 5: Self Reported Smoking**

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A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

Subject ID	Group	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10
2287	Active	15	15	12	11	10	10	10	11	10	10
2288	Placebo	20	20	19	20	17	17	18	18	17	17
2289	Active	15	15	15	15	15	15	15	15	15	15
2290	Placebo	10	10	10	25	25	25	25	20	20	20
2291	Active	35	35	35	35	35	30	30	30	27	30
2292	Placebo	20	20	20	20	25	25	30	20	20	20
2293	Placebo	20	20	18	19	18	18	17	16	17	15
2294	Active	30	30	28	25	25	20	20	25	35	35
2295	Active	20	20	15	15	12	12	12	10	10	8
2296	Active	15	10	10	8	7	5	2	2	2	0
2297	Placebo	20	18	20	18	18	16	16	17	16	16
2298	Placebo	23	20	20	19	17	18	16	16	15	12
2299	Active	11	11	7	8	7	8	10	12	12	10
2300	Placebo	20	20	17	20	19	16	16	16	17	17
2301	Active	30	30	30	30	30	30	30	20	20	20
2302	Placebo	20	20	20	19	18	18	17	15	15	14
2303	Active	25	20	20	20	18	18	18	15	15	15
2304	Placebo	25	20	20	20	18	18	18	20	18	20
2305	Placebo	25	20	20	20	18	18	20	20	18	20
2306	Active	44	38	30	30	30	30	6	6	6	6
3001	Placebo	8	6	6	7	10	8	8	8	8	7
3002	Placebo	25	15	20	20	15	15	20	18	15	20
3003	Active	18	18	19	14	15	17	18	19	18	19
3004	Active	31	25	23	24	24	22	23	20	20	21
3006	Placebo	20	20	20	18	18	20	18	18	18	15
3007	Active	15	15	15	15	15	15	13	10	15	15
3008	Active	7	6	6	7	7	7	10	10	10	9
3009	Placebo	25	30	30	20	30	20	25	30	30	30
3010	Placebo	10	10	12	11	9	12	7	10	10	6
3011	Active	15	10	10	0	0	5	5	5	5	7
3012	Placebo	17	15	15	16	15	17	18	15	14	15
3013	Active	15	20	20	25	25	25	15	20	18	15
3014	Active	25	25	20	20	20	20	20	20	20	20
3015	Active	40	40	40	40	35	40	40	35	30	30
3016	Placebo	20	15	15	15	15	15	12	12	12	12
3017	Placebo	20	20	20	20	15	15	15	18	20	20
3018	Placebo	30	30	25	25	25	25	25	25	25	25
3019	Active	25	20	20	20	20	20	20	20	20	20
3020	Placebo	35	35	32	32	32	32	35	32	32	30
3021	Active	25	25	25	25	22	22	20	20	20	20
3022	Placebo	20	20	20	20	15	15	20	20	20	20
3023	Active	20	20	20	20	20	20	20	18	18	16
3024	Placebo	40	40	35	35	35	35	35	35	35	30
3025	Placebo	20	20	20	20	15	15	15	15	15	15
3026	Placebo	20	20	20	20	20	20	20	20	20	20
3027	Placebo	30	30	30	30	30	30	20	20	20	20
3028	Active	40	40	40	40	40	40	35	35	35	35
3029	Active	30	30	30	30	30	30	26	26	26	25
3030	Active	40	40	40	40	35	35	35	35	35	30
3031	Active	20	20	20	18	18	18	18	18	18	16

**CONFIDENTIAL**

**Listing 5: Self Reported Smoking**

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A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

<b>Subject ID</b>	<b>Group</b>	<b>Week 1</b>	<b>Week 2</b>	<b>Week 3</b>	<b>Week 4</b>	<b>Week 5</b>	<b>Week 6</b>	<b>Week 7</b>	<b>Week 8</b>	<b>Week 9</b>	<b>Week 10</b>
3032	Active	40	40	40	40	40	40	35	35	35	30
3033	Placebo	20	20	20	20	20	20	18	18	18	16
3034	Active	20	20	20	20	20	20	15	15	15	15
3035	Placebo	20	18	20	18	20	20	18	18	20	22
3036	Placebo	15	16	20	20	20	20	14	14	20	20
3037	Placebo	15	15	15	15	10	18	17	17	17	17
3038	Active	20	20	20	18	20	18	10	10	10	10
3039	Placebo	6	7	7	7	6	4	5	7	6	6
3040	Active	35	35	40	35	35	35	35	35	35	40
3041	Placebo	30	30	30	28	30	30	25	25	25	25
3042	Active	30	30	30	30	30	25	25	25	25	25
3043	Placebo	15	15	15	15	15	15	14	14	14	14
3044	Active	10	10	10	10	10	10	10	10	9	9
3045	Active	20	15	15	15	15	15	15	10	10	15
3046	Placebo	40	40	40	30	30	30	30	30	30	30
3047	Active	10	10	7	15	20	15	12	15	8	10
3048	Placebo	15	15	10	12	15	15	15	15	13	15
3049	Placebo	20	19	19	18	18	18	15	15	13	13
3050	Active	20	18	16	16	15	15	16	16	17	15

**CONFIDENTIAL**

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**Average number of Cigarettes per day  
(Serbia)**

<b>Subject ID</b>	<b>Group</b>	<b>Week 11</b>	<b>Week 12</b>	<b>Week 13</b>	<b>Week 14</b>	<b>Week 15</b>	<b>Week 16</b>	<b>Week 17</b>	<b>Week 18</b>	<b>Week 19</b>	<b>Week 20</b>
1001	Placebo	29	30	30	30	35	35	35	35	35	35
1002	Placebo	23	20	20	20	20	25	20	27	10	10
1003	Active	20	20	20	20	20	20	20	20	12	10
1004	Active	8	8	.	.	.	.	.	.	.	.
1005	Active	8	10	10	10	10	10	10	10	10	10
1006	Placebo	15	15	15	15	15	12	12	12	20	20
1007	Active	.	.	.	.	.	.	.	.	.	.
1008	Active	30	30	30	30	30	30	30	30	30	30
1009	Placebo	19	18	20	20	20	20	20	20	15	15
1010	Placebo	20	20	16	16	16	15	15	15	25	25
1011	Active	50	50	25	20	20	20	20	20	20	20
1012	Placebo	20	20	20	20	20	20	20	20	20	20
1013	Active	15	20	10	20	15	15	15	10	15	15
1014	Active	25	25	25	25	25	20	20	20	20	20
1015	Active	25	25	25	25	25	25	25	25	.	.
1016	Placebo	25	28	25	28	22	20	23	26	18	16
1017	Placebo	22	22	20	23	20	25	25	25	.	.
1018	Placebo	.	.	.	.	.	.	.	.	.	.
1019	Active	16	16	14	14	14	14	16	16	16	17
1020	Placebo	25	25	25	20	25	25	25	25	.	.
1021	Active	8	8	10	8	8	10	8	8	.	.
1022	Placebo	.	.	.	.	.	.	.	.	.	.
1023	Active	5	4	4	4	4	4	4	4	4	5
1024	Placebo	.	.	30	30	30	30	30	30	.	.
1025	Placebo	8	8	3	5	5	7	8	6	5	7
1026	Placebo	.	.	.	.	.	.	.	.	.	.
1027	Placebo	20	20	20	20	20	20	20	20	20	20
1028	Active	20	20	15	15	15	15	15	15	15	15
1029	Active	15	30	30	30	30	30	30	30	.	.
1030	Active	10	10	10	10	10	10	10	10	10	10
1031	Active	23	25	23	23	22	22	23	24	25	24
1032	Active	.	.	.	.	.	.	.	.	.	.
1033	Placebo	5	5	6	10	10	10	8	8	8	7
1034	Active	.	.	.	.	.	.	.	.	.	.
1035	Placebo	12	12	9	8	8	9	9	10	8	8
1036	Placebo	.	.	.	.	.	.	.	.	.	.
1037	Placebo	11	10	7	6	8	10	8	10	8	8
1038	Active	10	8	10	10	10	10	10	5	0	0
1039	Placebo	.	.	.	.	.	.	.	.	.	.
1040	Active	.	.	.	.	.	.	.	.	.	.
1041	Placebo	15	15	15	15	15	15	15	15	.	.
1042	Active	10	10	20	20	30	30	30	30	.	.
1043	Placebo	10	10	10	11	12	11	9	8	6	7
1044	Active	.	.	.	.	.	.	.	.	.	.
1045	Active	.	.	.	.	.	.	.	.	.	.
1046	Placebo	10	10	10	10	10	10	10	10	.	.
1047	Active	15	15	25	25	25	25	25	25	.	.
1048	Placebo	35	35	35	35	35	35	35	35	.	.
1049	Placebo	32	32	35	35	35	35	35	35	.	.
1050	Active	12	10	10	10	10	10	10	10	.	.

**CONFIDENTIAL**

**Listing 5: Self Reported Smoking**

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**Average number of Cigarettes per day  
(Serbia)**

Subject ID	Group	Week 11	Week 12	Week 13	Week 14	Week 15	Week 16	Week 17	Week 18	Week 19	Week 20
1205	Placebo	10	10	10	10	10	12	12	12	10	10
1206	Placebo	.	.	.	.	.	.	.	.	.	.
1207	Active	.	.	.	.	.	.	.	.	.	.
1208	Active	15	15	15	15	20	20	18	18	.	.
1209	Active	3	3	.	.	.	.	.	.	.	.
1210	Placebo	15	15	15	14	15	12	10	15	10	12
1211	Active	25	25	.	.	.	.	.	.	.	.
1212	Active	3	3	4	4	3	4	8	8	8	8
1213	Placebo	20	20	20	20	15	18	18	18	.	.
1214	Placebo	15	15	15	15	15	15	15	15	15	16
1215	Active	13	13	13	14	13	13	13	14	12	10
1216	Placebo	10	10	10	10	10	10	10	10	8	5
1217	Active	15	15	15	15	15	15	15	15	.	.
1218	Active	.	.	.	.	.	.	.	.	.	.
1219	Active	.	.	.	.	.	.	.	.	.	.
1220	Placebo	12	12	14	13	12	12	15	12	12	12
1221	Placebo	16	15	15	14	15	15	15	15	.	.
1222	Placebo	20	20	12	13	12	14	12	12	.	.
1223	Active	15	15	15	18	18	15	17	15	15	12
1224	Placebo	15	20	15	15	15	15	15	15	10	10
1225	Active	20	20	17	17	18	18	18	18	.	.
1226	Placebo	15	15	15	15	15	15	12	12	12	12
1227	Active	8	12	8	8	8	8	8	8	.	.
1228	Placebo	4	3	4	4	0	0	4	6	.	.
1229	Placebo	20	20	12	10	15	10	12	12	.	.
1230	Placebo	17	10	15	13	15	13	13	13	12	10
1231	Placebo	13	14	15	14	17	13	14	15	12	12
1232	Active	.	.	.	.	.	.	.	.	.	.
1233	Active	10	10	8	8	7	6	6	7	10	8
1234	Active	40	40	.	.	.	.	.	.	.	.
1235	Active	5	3	2	2	2	1	1	1	2	1
1236	Active	.	.	.	.	.	.	.	.	.	.
1237	Placebo	16	16	15	15	15	15	15	15	15	13
1238	Active	12	13	12	12	12	11	11	11	7	7
1239	Placebo	15	15	17	17	17	17	17	17	12	12
1240	Placebo	10	10	9	9	9	9	9	9	9	8
1241	Placebo	.	.	.	.	.	.	.	.	.	.
1242	Active	10	10	13	13	13	13	13	13	10	10
1243	Placebo	10	10	10	10	10	10	10	10	10	10
1244	Active	15	15	13	13	13	13	13	13	14	15
1245	Placebo	7	7	4	4	4	4	4	4	8	9
1246	Active	22	25	23	24	23	23	23	23	25	25
1247	Placebo	18	15	15	14	14	14	14	14	15	15
1325	Placebo	6	4	4	4	2	2	1	0	0	0
1326	Placebo	16	15	14	12	12	11	12	11	10	10
1327	Active	21	20	16	16	18	16	16	16	15	15
1328	Active	22	22	19	19	16	18	16	15	8	4
1329	Active	16	15	15	14	13	13	12	10	10	8
1330	Placebo	16	15	15	15	12	10	10	10	10	9
1331	Active	17	16	16	13	13	9	10	10	10	10

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**Listing 5: Self Reported Smoking**

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**Average number of Cigarettes per day  
(Serbia)**

Subject ID	Group	Week 11	Week 12	Week 13	Week 14	Week 15	Week 16	Week 17	Week 18	Week 19	Week 20
1332	Active	20	20	16	16	18	18	15	15	14	14
1333	Placebo	15	15	14	14	12	12	9	9	10	10
1334	Placebo	32	30	26	24	22	22	20	20	20	19
1335	Active	23	20	20	19	19	15	15	12	12	11
1336	Placebo	15	13	12	13	10	10	9	9	10	9
1337	Active	7	12	9	9	10	6	8	8	8	7
1338	Active	20	19	18	18	16	15	13	13	12	12
1339	Active	18	18	16	14	13	13	12	12	12	12
1340	Placebo	30	28	24	23	23	21	20	20	20	16
1341	Placebo	18	18	16	16	16	12	12	12	12	12
1342	Placebo	15	14	15	13	13	12	15	12	12	12
1343	Active	12	12	12	12	10	11	10	10	8	6
1344	Placebo	15	14	14	14	12	12	10	10	8	7
1345	Active	10	10	10	8	8	8	7	7	6	6
1346	Placebo	15	15	15	13	13	12	12	10	10	10
1347	Active	20	20	20	20	20	20	20	20	20	20
1348	Placebo	9	9	9	10	8	9	9	8	8	7
1349	Placebo	15	14	15	15	15	15	15	15	15	15
2001	Placebo	10	10	10	10	10	10	10	10	12	10
2002	Placebo	20	20	20	20	20	20	20	20	20	20
2003	Active	10	10	10	10	10	10	10	10	10	10
2004	Active	30	25	30	30	30	40	40	40	40	40
2005	Active	10	10	10	10	10	10	10	10	10	12
2006	Placebo	15	15	15	15	12	15	12	12	12	15
2007	Active	9	9	10	10	12	15	15	15	12	15
2008	Active	15	15	13	13	15	15	15	15	15	15
2009	Placebo	15	15	15	15	12	12	15	15	15	15
2010	Placebo	18	18	20	20	18	22	20	20	20	20
2011	Active	15	15	15	15	12	15	12	12	15	15
2012	Placebo	20	20	20	18	20	15	18	18	16	16
2013	Active	25	25	25	28	26	25	25	22	21	21
2014	Active	10	10	10	10	10	10	10	10	10	10
2015	Active	15	15	13	13	14	13	13	14	15	15
2016	Placebo	15	15	12	12	12	11	11	11	5	5
2017	Placebo	15	15	10	15	10	10	10	10	20	20
2018	Placebo	12	12	14	14	13	14	14	14	15	15
2019	Active	20	20	18	18	8	9	12	9	10	10
2020	Placebo	12	12	12	15	15	12	12	12	12	12
2021	Active	20	20	20	20	15	15	18	15	15	15
2022	Placebo	20	20	20	20	20	22	22	25	25	20
2023	Active	15	15	15	15	15	15	15	15	20	20
2024	Placebo	20	20	20	20	15	15	11	11	15	15
2025	Placebo	15	15	15	15	15	15	18	15	12	10
2026	Placebo	13	15	11	12	13	13	12	14	10	7
2027	Placebo	10	10	9	9	8	10	8	8	5	4
2028	Active	12	15	20	14	16	8	10	10	7	7
2029	Active	10	15	15	10	20	20	15	10	15	15
2030	Active	18	20	22	20	18	22	20	20	17	15
2031	Active	10	10	10	10	10	11	11	10	9	7
2032	Active	20	20	20	20	20	21	18	18	18	15

**CONFIDENTIAL**

**Listing 5: Self Reported Smoking**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

Subject ID	Group	Week 11	Week 12	Week 13	Week 14	Week 15	Week 16	Week 17	Week 18	Week 19	Week 20
2033	Placebo	15	15	15	15	12	12	12	12	10	10
2034	Active	10	15	10	15	10	15	10	10	10	7
2035	Placebo	25	25	20	20	20	5	15	15	30	30
2036	Placebo	20	20	20	18	18	15	18	16	12	12
2037	Placebo	22	25	25	22	22	25	25	25	.	.
2038	Active	18	18	20	20	18	20	20	20	.	.
2039	Placebo	15	15	15	18	15	15	15	13	8	7
2040	Active	15	15	18	15	16	14	14	14	12	10
2041	Placebo	20	20	15	15	15	18	15	15	.	.
2042	Active	9	9	15	15	15	15	15	15	15	10
2043	Placebo	25	20	.	.	.	.	.	.	.	.
2044	Active	20	22	20	20	20	21	24	21	15	15
2045	Active	20	20	20	20	22	20	20	18	15	15
2046	Placebo	14	14	15	16	17	10	18	17	15	14
2047	Active	15	15	15	12	12	12	12	10	10	10
2048	Placebo	12	12	9	9	8	8	8	8	8	6
2049	Placebo	3	4	3	3	4	3	10	5	3	5
2050	Active	18	18	18	18	15	15	14	12	18	10
2205	Active	24	24	20	18	18	16	15	15	15	15
2206	Placebo	16	16	16	16	15	14	14	13	12	10
2207	Placebo	20	20	20	18	17	15	15	15	12	12
2208	Active	20	18	16	15	15	15	15	15	12	12
2209	Active	16	16	15	15	13	13	12	12	10	10
2210	Placebo	12	10	10	10	10	10	10	8	7	7
2211	Placebo	20	20	20	20	20	15	5	7	0	11
2212	Placebo	20	20	20	18	16	16	16	16	15	14
2213	Active	15	15	13	12	11	12	11	12	12	12
2214	Active	20	20	18	18	18	18	16	14	12	12
2215	Active	25	25	23	23	20	20	21	20	16	15
2216	Placebo	30	30	27	26	24	24	22	20	20	18
2217	Active	23	23	20	20	18	20	16	14	14	14
2218	Placebo	16	16	14	14	13	13	10	10	10	10
2219	Active	15	15	15	14	13	12	11	10	10	10
2220	Placebo	20	20	21	23	20	22	22	21	12	12
2221	Placebo	18	18	19	19	15	15	13	13	12	12
2222	Active	12	12	12	12	12	10	10	8	7	7
2223	Placebo	10	10	9	9	8	7	5	9	5	5
2224	Placebo	19	17	16	16	13	12	12	12	12	12
2225	Placebo	12	10	10	11	11	10	10	10	10	10
2226	Active	20	20	20	20	20	20	20	20	20	20
2227	Active	10	10	10	10	7	11	5	8	8	7
2228	Active	18	18	18	16	16	14	14	11	10	10
2229	Placebo	18	18	18	16	16	15	14	12	12	11
2230	Active	16	15	14	14	13	12	10	10	10	10
2231	Active	3	4	8	7	9	7	9	8	8	7
2232	Placebo	15	15	13	12	15	10	10	10	10	10
2233	Placebo	28	28	26	25	28	24	22	20	20	20
2234	Active	50	50	45	40	37	35	33	30	30	30
2235	Placebo	22	23	22	20	18	18	19	16	15	15
2236	Placebo	11	11	10	11	10	8	8	7	7	7

**CONFIDENTIAL**

**Listing 5: Self Reported Smoking**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

Subject ID	Group	Week 11	Week 12	Week 13	Week 14	Week 15	Week 16	Week 17	Week 18	Week 19	Week 20
2237	Placebo	16	16	13	14	12	11	10	10	10	10
2238	Active	10	10	10	9	8	8	7	5	5	5
2239	Active	20	20	20	18	18	18	17	16	15	15
2240	Active	15	15	14	14	13	12	12	10	10	10
2241	Active	17	15	15	16	16	15	15	15	14	14
2242	Active	8	8	8	7	8	7	8	6	8	7
2243	Placebo	15	15	15	12	15	10	10	10	10	10
2244	Placebo	10	10	8	8	8	8	8	8	8	7
2245	Active	12	12	12	11	11	10	10	8	7	7
2246	Placebo	15	12	12	12	10	10	10	10	10	10
2247	Active	8	8	7	7	10	10	10	8	8	10
2248	Active	15	15	13	13	13	12	11	10	10	10
2249	Placebo	18	18	18	17	16	15	15	15	14	14
2250	Placebo	10	10	9	8	8	8	6	5	5	5
2251	Active	15	15	10	12	10	15	10	10	15	10
2252	Placebo	22	22	20	18	18	16	17	16	15	15
2253	Active	17	12	15	14	16	14	15	13	15	10
2254	Placebo	15	15	10	10	15	10	10	15	15	15
2255	Active	20	20	25	25	25	25	25	25	20	20
2256	Placebo	18	18	17	16	14	16	12	10	10	10
2257	Active	20	0	0	0	0	0	0	0	0	0
2258	Placebo	10	10	8	5	7	3	5	7	4	8
2259	Placebo	16	15	15	14	13	13	10	10	10	10
2260	Placebo	16	16	16	14	14	14	13	13	12	12
2261	Active	15	15	.	.	18	18	17	17	17	16
2262	Active	10	9	10	12	6	8	8	10	0	0
2263	Placebo	25	25	27	30	30	30	30	30	30	30
2264	Active	10	10	10	10	11	12	10	11	11	10
2265	Active	35	35	35	32	28	28	26	25	25	25
2266	Active	15	15	15	13	13	11	10	10	10	10
2267	Active	35	35	35	32	32	28	25	22	20	20
2268	Placebo	13	12	12	10	10	11	13	13	11	12
2269	Placebo	10	10	10	10	10	10	12	10	10	12
2270	Placebo	10	10	10	10	10	10	10	10	10	10
2271	Placebo	10	9	10	10	10	10	10	10	10	10
2272	Placebo	40	35	35	35	35	30	30	30	30	30
2273	Active	35	30	25	25	30	30	35	30	25	25
2274	Placebo	10	10	10	10	10	8	8	9	5	5
2275	Active	9	10	9	9	10	10	9	9	8	0
2276	Active	20	20	20	15	20	20	20	20	20	20
2277	Active	2	2	0	0	0	0	0	0	0	0
2278	Active	10	10	20	20	18	18	8	8	18	15
2279	Placebo	30	30	30	20	20	20	20	20	20	20
2280	Placebo	8	7	7	6	7	6	5	6	6	6
2281	Active	10	10	10	10	10	10	10	10	10	12
2282	Placebo	15	15	15	15	20	15	15	15	15	15
2283	Placebo	25	25	25	25	25	23	23	25	20	25
2284	Active	28	40	40	40	40	40	35	30	30	27
2285	Active	10	15	10	15	20	15	15	10	15	10
2286	Placebo	13	15	15	15	15	15	15	13	15	15

**CONFIDENTIAL**

**Listing 5: Self Reported Smoking**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

Subject ID	Group	Week 11	Week 12	Week 13	Week 14	Week 15	Week 16	Week 17	Week 18	Week 19	Week 20
2287	Active	10	10	10	10	10	10	10	10	5	5
2288	Placebo	20	20	20	20	17	17	20	15	12	
2289	Active	15	15	15	15	20	20	20	20	20	20
2290	Placebo	20	20	20	20	20	20	20	10	10	
2291	Active	30	30	30	27	25	30	30	30	25	20
2292	Placebo	30	30	30	25	25	20	25	30	30	30
2293	Placebo	15	14	15	15	15	14	15	10	10	
2294	Active	34	33	33	30	30	30	30	30	30	30
2295	Active	8	8	8	5	5	5	5	5	0	0
2296	Active	0	0	1	1	1	2	2	1	0	0
2297	Placebo	15	15	15	15	15	15	15	10	10	
2298	Placebo	15	15	12	12	10	10	10	10	10	
2299	Active	12	10	20	18	20	18	21	22	15	20
2300	Placebo	18	17	15	15	15	15	15	10	10	
2301	Active	20	20	20	20	20	20	20	20	20	
2302	Placebo	15	13	12	12	12	15	12	12	10	
2303	Active	15	15	15	15	15	15	15	15	15	
2304	Placebo	18	18	15	15	15	15	15	20	20	
2305	Placebo	18	18	15	15	15	15	15	10	8	
2306	Active	6	6	6	6	6	6	6	6	6	
3001	Placebo	6	8	8	7	6	8	8	8	8	
3002	Placebo	20	20	20	15	10	12	10	10	10	
3003	Active	15	12	14	14	18	19	14	16	14	
3004	Active	20	18	18	17	17	17	18	17	17	
3006	Placebo	15	12	12	12	11	12	11	10	10	
3007	Active	15	15	15	15	15	16	9	3	2	
3008	Active	8	7	10	9	12	11	8	8	8	
3009	Placebo	30	30	30	20	20	25	20	20	15	
3010	Placebo	10	8	5	8	10	7	6	7	6	
3011	Active	5	8	10	8	8	8	8	7	6	
3012	Placebo	15	15	15	15	15	15	15	14	14	
3013	Active	18	15	15	15	15	15	15	15	15	
3014	Active	20	18	18	20	19	19	17	15	12	
3015	Active	30	30	28	28	28	28	28	22	22	
3016	Placebo	12	12	12	12	10	12	10	10	9	
3017	Placebo	23	20	20	20	20	18	15	14	12	
3018	Placebo	25	25	20	20	20	20	20	20	20	
3019	Active	20	20	10	10	8	3	2	10	10	
3020	Placebo	30	30	30	25	25	25	25	20	18	
3021	Active	20	20	20	18	18	18	18	18	15	
3022	Placebo	20	20	.	.	.	.	.	.	.	
3023	Active	16	16	10	15	12	12	12	12	12	
3024	Placebo	30	30	25	25	25	22	22	20	20	
3025	Placebo	15	15	15	15	10	10	10	10	10	
3026	Placebo	20	20	20	20	18	18	15	15	12	
3027	Placebo	20	20	20	20	18	18	16	17	15	
3028	Active	30	30	30	26	26	24	24	20	20	
3029	Active	25	26	24	22	22	20	18	18	16	
3030	Active	30	30	25	25	25	25	20	20	20	
3031	Active	10	12	15	15	15	14	14	14	10	

**CONFIDENTIAL**

**Listing 5: Self Reported Smoking**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

<b>Subject ID</b>	<b>Group</b>	<b>Week 11</b>	<b>Week 12</b>	<b>Week 13</b>	<b>Week 14</b>	<b>Week 15</b>	<b>Week 16</b>	<b>Week 17</b>	<b>Week 18</b>	<b>Week 19</b>	<b>Week 20</b>
3032	Active	30	28	28	28	30	30	28	28	28	26
3033	Placebo	20	18	15	15	14	14	13	12	10	10
3034	Active	15	15	15	15	13	14	13	12	10	10
3035	Placebo	22	22	18	20	20	20	17	17	14	15
3036	Placebo	20	15	15	15	12	12	10	10	10	9
3037	Placebo	17	15	15	15	15	15	15	10	10	7
3038	Active	10	10	10	10	10	10	10	10	10	10
3039	Placebo	4	7	7	6	7	8	7	8	7	7
3040	Active	35	35	40	30	28	25	23	23	20	20
3041	Placebo	25	25	25	22	22	20	20	18	16	15
3042	Active	25	25	22	22	20	18	18	17	15	14
3043	Placebo	13	13	12	12	10	10	7	7	7	7
3044	Active	10	10	10	9	9	8	8	8	7	7
3045	Active	15	15	10	10	10	10	10	9	9	9
3046	Placebo	30	30	23	23	19	19	20	20	20	18
3047	Active	15	15	14	13	13	12	10	10	10	10
3048	Placebo	15	15	14	14	12	11	9	9	7	7
3049	Placebo	13	12	12	12	12	13	12	12	12	12
3050	Active	13	14	12	11	10	11	10	10	9	10

**CONFIDENTIAL**

**Listing 5: Self Reported Smoking**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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**Average number of Cigarettes per day  
(Serbia)**

Subject ID	Group	Week 21	Week 22	Week 23	Week 24	Week 25	Week 26	Week 27	Week 28	Week 29	Week 30
1001	Placebo	40	37	34	25	.	.	.	.	.	.
1002	Placebo	10	10	10	10	18	17	18	18	18	17
1003	Active	10	10	10	10	15	15	15	15	15	15
1004	Active	.	.	.	.	.	.	.	.	.	.
1005	Active	10	10	10	10	13	10	10	10	10	10
1006	Placebo	20	20	20	20	.	.	.	.	.	.
1007	Active	.	.	.	.	.	.	.	.	.	.
1008	Active	30	30	30	30	20	20	20	20	20	20
1009	Placebo	15	15	15	15	15	15	15	15	15	15
1010	Placebo	25	25	25	25	.	.	.	.	.	.
1011	Active	20	20	20	20	.	.	.	.	.	.
1012	Placebo	30	30	35	35	.	.	.	.	.	.
1013	Active	15	17	12	15	.	.	.	.	.	.
1014	Active	20	20	20	20	.	.	.	.	.	.
1015	Active	.	.	.	.	.	.	.	.	.	.
1016	Placebo	15	15	15	14	10	12	9	8	8	8
1017	Placebo	.	.	.	.	.	.	.	.	.	.
1018	Placebo	.	.	.	.	.	.	.	.	.	.
1019	Active	17	17	17	15	14	14	17	17	17	17
1020	Placebo	.	.	.	.	.	.	.	.	.	.
1021	Active	.	.	.	.	.	.	.	.	.	.
1022	Placebo	.	.	.	.	.	.	.	.	.	.
1023	Active	5	7	4	7	5	8	7	4	6	6
1024	Placebo	.	.	.	.	.	.	.	.	.	.
1025	Placebo	5	10	8	8	8	6	7	9	10	6
1026	Placebo	.	.	.	.	.	.	.	.	.	.
1027	Placebo	20	20	20	15	18	15	20	15	15	15
1028	Active	15	15	15	15	15	15	15	15	15	15
1029	Active	.	.	.	.	.	.	.	.	.	.
1030	Active	10	10	10	10	10	10	10	10	10	10
1031	Active	23	20	0	0	10	18	15	16	15	20
1032	Active	.	.	.	.	.	.	.	.	.	.
1033	Placebo	6	10	8	8	10	10	8	7	7	7
1034	Active	.	.	.	.	.	.	.	.	.	.
1035	Placebo	9	8	7	7	12	12	10	11	14	12
1036	Placebo	.	.	.	.	.	.	.	.	.	.
1037	Placebo	8	8	6	8	7	8	6	6	6	5
1038	Active	0	0	0	0	0	0	0	0	0	0
1039	Placebo	.	.	.	.	.	.	.	.	.	.
1040	Active	.	.	.	.	.	.	.	.	.	.
1041	Placebo	.	.	.	.	.	.	.	.	.	.
1042	Active	.	.	.	.	.	.	.	.	.	.
1043	Placebo	10	11	12	12	.	.	.	.	.	.
1044	Active	.	.	.	.	.	.	.	.	.	.
1045	Active	.	.	.	.	.	.	.	.	.	.
1046	Placebo	.	.	.	.	.	.	.	.	.	.
1047	Active	.	.	.	.	.	.	.	.	.	.
1048	Placebo	.	.	.	.	.	.	.	.	.	.
1049	Placebo	.	.	.	.	.	.	.	.	.	.
1050	Active	.	.	.	.	.	.	.	.	.	.

**CONFIDENTIAL**

**Listing 5: Self Reported Smoking**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

Subject ID	Group	Week 21	Week 22	Week 23	Week 24	Week 25	Week 26	Week 27	Week 28	Week 29	Week 30
1205	Placebo	10	12	12	12	10	10	10	10	10	10
1206	Placebo	.	.	.	.	.	.	.	.	.	.
1207	Active	.	.	.	.	.	.	.	.	.	.
1208	Active	.	.	.	.	.	.	.	.	.	.
1209	Active	.	.	.	.	.	.	.	.	.	.
1210	Placebo	10	10	12	10	10	10	10	10	10	10
1211	Active	.	.	.	.	.	.	.	.	.	.
1212	Active	9	8	8	8	7	6	6	6	7	7
1213	Placebo	.	.	.	.	.	.	.	.	.	.
1214	Placebo	15	15	15	15	16	15	15	15	15	15
1215	Active	8	8	8	8	.	.	.	.	.	.
1216	Placebo	9	5	8	8	10	10	10	10	10	10
1217	Active	.	.	.	.	.	.	.	.	.	.
1218	Active	.	.	.	.	.	.	.	.	.	.
1219	Active	.	.	.	.	.	.	.	.	.	.
1220	Placebo	12	12	12	12	10	10	8	8	8	8
1221	Placebo	.	.	.	.	.	.	.	.	.	.
1222	Placebo	.	.	.	.	.	.	.	.	.	.
1223	Active	15	15	12	12	15	15	15	18	18	15
1224	Placebo	10	10	10	10	10	10	10	8	8	7
1225	Active	.	.	.	.	.	.	.	.	.	.
1226	Placebo	12	10	10	10	7	7	7	7	7	7
1227	Active	.	.	.	.	.	.	.	.	.	.
1228	Placebo	.	.	.	.	.	.	.	.	.	.
1229	Placebo	.	.	.	.	.	.	.	.	.	.
1230	Placebo	9	8	8	8	8	8	7	8	6	7
1231	Placebo	13	10	10	10	.	.	.	.	.	.
1232	Active	.	.	.	.	.	.	.	.	.	.
1233	Active	10	10	10	10	10	8	9	8	7	5
1234	Active	.	.	.	.	.	.	.	.	.	.
1235	Active	0	1	1	1	2	2	2	2	2	2
1236	Active	.	.	.	.	.	.	.	.	.	.
1237	Placebo	15	15	15	13	13	13	13	13	13	13
1238	Active	5	7	6	7	7	7	7	7	7	7
1239	Placebo	12	10	12	12	10	10	10	10	10	10
1240	Placebo	10	6	9	9	9	9	9	9	9	9
1241	Placebo	.	.	.	.	.	.	.	.	.	.
1242	Active	10	10	10	10	10	10	10	10	10	10
1243	Placebo	10	10	10	10	10	10	10	10	10	10
1244	Active	12	12	14	14	14	14	14	14	14	14
1245	Placebo	9	8	8	8	8	8	8	8	8	8
1246	Active	25	25	25	25	20	20	20	20	20	20
1247	Placebo	15	15	15	15	15	13	13	14	13	13
1325	Placebo	0	0	0	0	0	0	0	0	0	0
1326	Placebo	10	9	9	10	10	9	9	9	10	10
1327	Active	14	14	13	14	10	14	12	12	12	10
1328	Active	4	4	2	2	1	1	0	0	0	0
1329	Active	8	9	10	9	9	9	10	10	9	9
1330	Placebo	10	10	10	9	10	10	9	10	10	9
1331	Active	7	7	3	10	10	10	8	8	9	9

**CONFIDENTIAL**

**Listing 5: Self Reported Smoking**

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**Average number of Cigarettes per day  
(Serbia)**

Subject ID	Group	Week 21	Week 22	Week 23	Week 24	Week 25	Week 26	Week 27	Week 28	Week 29	Week 30
1332	Active	14	10	10	12	12	12	10	10	10	10
1333	Placebo	10	10	10	10	9	8	8	9	9	9
1334	Placebo	15	19	20	20	18	19	19	18	18	18
1335	Active	12	13	15	11	11	10	10	5	7	10
1336	Placebo	9	10	9	10	10	10	10	10	10	10
1337	Active	10	9	10	9	9	8	8	9	7	
1338	Active	11	11	10	10	10	9	12	10	10	
1339	Active	10	8	12	12	12	10	8	8	11	
1340	Placebo	16	20	18	18	17	16	17	16	15	15
1341	Placebo	12	12	10	10	10	10	6	10	10	
1342	Placebo	12	13	13	12	.	.	.	.	.	
1343	Active	6	5	5	5	5	4	2	4	4	
1344	Placebo	8	7	6	5	5	4	2	4	3	
1345	Active	5	5	6	5	5	4	2	2	1	1
1346	Placebo	8	8	10	9	9	9	7	7	8	
1347	Active	20	20	20	20	.	.	.	.	.	
1348	Placebo	8	8	10	10	.	.	.	.	.	
1349	Placebo	15	15	15	14	10	10	10	10	10	10
2001	Placebo	10	9	9	9	9	8	9	9	9	9
2002	Placebo	20	20	18	18	18	18	17	18	17	18
2003	Active	10	10	10	10	10	10	10	10	10	10
2004	Active	40	40	40	.	.	.	.	.	.	.
2005	Active	12	12	12	.	.	.	.	.	.	.
2006	Placebo	12	15	15	17	.	.	.	.	.	.
2007	Active	15	15	15	12	.	.	.	.	.	.
2008	Active	15	12	15	15	.	.	.	.	.	.
2009	Placebo	12	12	12	10	.	.	.	.	.	.
2010	Placebo	20	20	20	20	20	18	18	18	18	18
2011	Active	14	12	12	10	.	.	.	.	.	.
2012	Placebo	16	15	15	15	.	.	.	.	.	.
2013	Active	20	18	20	20	.	.	.	.	.	.
2014	Active	12	10	15	15	.	.	.	.	.	.
2015	Active	14	13	13	13	.	.	.	.	.	.
2016	Placebo	5	5	5	5	5	3	3	0	2	2
2017	Placebo	25	25	20	25	.	.	.	.	.	.
2018	Placebo	12	12	14	12	.	.	.	.	.	.
2019	Active	12	10	10	10	.	.	.	.	.	.
2020	Placebo	12	10	10	10	.	.	.	.	.	.
2021	Active	15	15	15	15	15	14	14	14	14	14
2022	Placebo	18	20	20	20	20	18	18	18	18	18
2023	Active	18	20	20	18	.	.	.	.	.	.
2024	Placebo	15	15	15	15	.	.	.	.	.	.
2025	Placebo	10	9	10	9	9	9	9	9	9	9
2026	Placebo	7	7	7	7	7	7	7	6	7	6
2027	Placebo	5	4	4	4	5	4	4	5	5	5
2028	Active	6	7	8	7	5	5	3	0	2	0
2029	Active	10	15	10	10	10	10	10	10	10	10
2030	Active	15	14	15	14	15	14	14	13	13	13
2031	Active	7	7	7	7	7	7	7	7	7	7
2032	Active	15	15	14	14	14	14	15	15	14	14

**CONFIDENTIAL**

**Listing 5: Self Reported Smoking**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

<b>Subject ID</b>	<b>Group</b>	<b>Week 21</b>	<b>Week 22</b>	<b>Week 23</b>	<b>Week 24</b>	<b>Week 25</b>	<b>Week 26</b>	<b>Week 27</b>	<b>Week 28</b>	<b>Week 29</b>	<b>Week 30</b>
2033	Placebo	10	9	9	9	10	10	10	9	10	10
2034	Active	7	7	5	5	.	.	.	.	.	.
2035	Placebo	25	25	25	25	25	30	25	30	30	28
2036	Placebo	12	10	10	10	10	12	13	12	10	12
2037	Placebo	.	.	.	.	.	.	.	.	.	.
2038	Active	.	.	.	.	.	.	.	.	.	.
2039	Placebo	7	7	7	7	8	8	9	9	8	9
2040	Active	10	10	10	10	.	.	.	.	.	.
2041	Placebo	.	.	.	.	.	.	.	.	.	.
2042	Active	10	10	10	10	10	15	15	10	10	10
2043	Placebo	.	.	.	.	.	.	.	.	.	.
2044	Active	14	15	15	15	15	15	14	14	15	15
2045	Active	15	15	15	15	15	14	14	14	15	15
2046	Placebo	15	14	15	14	.	.	.	.	.	.
2047	Active	8	7	7	6	3	3	4	3	3	3
2048	Placebo	6	7	8	11	10	7	8	9	9	8
2049	Placebo	7	6	7	7	7	7	8	7	7	8
2050	Active	10	10	10	9	9	10	10	10	10	10
2205	Active	14	14	15	14	14	14	14	13	13	14
2206	Placebo	10	10	10	10	10	10	10	10	10	10
2207	Placebo	12	12	12	12	12	12	12	11	12	12
2208	Active	12	11	11	11	11	11	10	10	11	11
2209	Active	10	10	10	10	10	10	10	10	10	10
2210	Placebo	7	6	7	6	3	1	0	1	0	0
2211	Placebo	13	9	7	7	10	10	10	10	12	9
2212	Placebo	15	14	14	14	14	14	13	13	14	13
2213	Active	12	12	12	12	12	12	12	12	12	12
2214	Active	12	12	12	12	12	12	11	11	11	11
2215	Active	15	15	15	15	15	15	15	15	15	10
2216	Placebo	18	20	18	18	18	18	18	20	20	18
2217	Active	15	14	14	14	14	13	13	14	15	13
2218	Placebo	10	9	10	9	10	10	9	10	9	10
2219	Active	10	10	10	10	10	10	10	10	11	10
2220	Placebo	12	12	12	12	10	9	8	8	7	6
2221	Placebo	12	11	12	12	12	11	11	10	10	11
2222	Active	7	7	7	7	7	7	6	6	6	6
2223	Placebo	5	5	5	5	5	5	5	5	5	5
2224	Placebo	10	11	11	11	11	11	12	12	12	11
2225	Placebo	10	10	10	10	8	8	7	8	8	9
2226	Active	18	20	20	20	20	20	19	18	18	20
2227	Active	9	10	9	9	9	9	8	8	9	9
2228	Active	10	10	10	10	10	10	8	8	9	10
2229	Placebo	11	10	12	10	10	10	10	9	9	10
2230	Active	9	9	10	10	9	9	8	8	10	10
2231	Active	7	7	7	7	7	7	7	7	7	7
2232	Placebo	10	10	9	10	10	8	10	10	9	10
2233	Placebo	19	19	20	19	19	18	18	19	20	18
2234	Active	30	30	28	30	30	30	28	30	30	28
2235	Placebo	14	15	15	15	15	15	14	12	12	12
2236	Placebo	5	5	7	6	6	7	5	5	7	6

**CONFIDENTIAL**

**Listing 5: Self Reported Smoking**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

Subject ID	Group	Week 21	Week 22	Week 23	Week 24	Week 25	Week 26	Week 27	Week 28	Week 29	Week 30
2237	Placebo	10	10	10	10	10	10	10	10	10	10
2238	Active	5	5	5	5	5	5	4	4	4	5
2239	Active	15	15	14	15	15	14	14	13	14	13
2240	Active	10	10	10	10	9	10	9	9	10	9
2241	Active	14	14	14	14	13	13	12	14	12	12
2242	Active	6	6	6	6	6	5	4	5	6	5
2243	Placebo	9	10	9	9	9	9	10	8	9	8
2244	Placebo	8	8	8	8	8	9	7	7	7	8
2245	Active	7	7	0	7	0	0	0	0	0	0
2246	Placebo	10	10	10	10	10	10	10	10	10	10
2247	Active	7	7	5	5	5	5	5	5	5	5
2248	Active	10	9	9	9	10	9	9	7	8	7
2249	Placebo	14	12	12	12	12	12	10	10	12	12
2250	Placebo	5	5	5	5	5	5	5	5	5	5
2251	Active	10	10	10	10	10	10	9	10	10	9
2252	Placebo	15	14	14	15	15	12	12	13	13	13
2253	Active	8	9	10	7	10	8	7	5	9	8
2254	Placebo	12	10	12	15	15	15	14	15	12	15
2255	Active	20	20	20	20	.	.	.	.	.	.
2256	Placebo	9	10	10	10	10	9	10	10	9	9
2257	Active	0	0	0	0	0	0	0	0	0	0
2258	Placebo	7	3	8	6	8	7	7	5	8	6
2259	Placebo	10	10	8	8	8	7	8	7	6	5
2260	Placebo	12	10	10	12	10	10	11	11	10	10
2261	Active	15	20	20	20	.	.	.	.	.	.
2262	Active	0	0	0	0	0	0	0	0	0	0
2263	Placebo	30	30	30	30	.	.	.	.	.	.
2264	Active	10	10	11	10	.	.	.	.	.	.
2265	Active	22	22	22	22	19	19	18	19	18	18
2266	Active	9	8	9	10	8	8	9	8	9	9
2267	Active	20	20	20	20	15	15	15	20	20	16
2268	Placebo	12	12	11	10	.	.	.	.	.	.
2269	Placebo	10	10	12	15	.	.	.	.	.	.
2270	Placebo	10	10	5	0	0	0	0	0	0	0
2271	Placebo	10	10	10	9	7	7	7	5	5	5
2272	Placebo	30	30	30	30	.	.	.	.	.	.
2273	Active	25	25	25	25	.	.	.	.	.	.
2274	Placebo	5	5	5	5	10	10	10	10	10	10
2275	Active	0	0	0	0	0	0	0	0	0	0
2276	Active	15	15	15	15	.	.	.	.	.	.
2277	Active	0	0	0	0	0	0	0	0	0	0
2278	Active	15	18	8	18	.	.	.	.	.	.
2279	Placebo	20	25	20	25	20	20	18	15	15	15
2280	Placebo	6	5	6	6	5	6	5	6	5	4
2281	Active	15	15	15	15	.	.	.	.	.	.
2282	Placebo	15	15	15	15	15	15	15	15	15	15
2283	Placebo	25	25	25	25	.	.	.	.	.	.
2284	Active	25	25	27	27	.	.	.	.	.	.
2285	Active	10	15	10	10	.	.	.	.	.	.
2286	Placebo	13	13	13	13	.	.	.	.	.	.

**CONFIDENTIAL**

**Listing 5: Self Reported Smoking**

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A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

Subject ID	Group	Week 21	Week 22	Week 23	Week 24	Week 25	Week 26	Week 27	Week 28	Week 29	Week 30
2287	Active	5	5	5	5	5	5	5	5	5	5
2288	Placebo	12	10	10	10	.	.	.	.	.	.
2289	Active	20	20	20	20	20	20	20	20	20	20
2290	Placebo	10	10	10	10	5	5	5	5	5	5
2291	Active	15	15	14	15	10	10	10	10	10	10
2292	Placebo	30	30	30	30	.	.	.	.	.	.
2293	Placebo	10	10	10	10	10	10	10	9	10	10
2294	Active	30	30	30	30	.	.	.	.	.	.
2295	Active	0	0	0	0	0	0	0	0	0	0
2296	Active	0	0	0	0	0	0	0	0	0	0
2297	Placebo	10	10	10	10	10	10	10	10	10	10
2298	Placebo	10	0	10	10	10	10	10	10	9	10
2299	Active	23	25	20	20	.	.	.	.	.	.
2300	Placebo	10	9	10	10	10	10	9	10	7	10
2301	Active	20	20	20	20	.	.	.	.	.	.
2302	Placebo	10	8	8	8	8	8	8	5	5	5
2303	Active	15	15	15	15	.	.	.	.	.	.
2304	Placebo	20	20	20	.	.	.	.	.	.	.
2305	Placebo	5	5	0	0	0	0	0	0	0	0
2306	Active	6	6	6	6	5	5	5	5	5	5
3001	Placebo	8	8	6	8	8	8	8	8	8	8
3002	Placebo	10	10	5	6	5	10	10	10	10	10
3003	Active	10	12	14	13	14	15	15	13	14	15
3004	Active	13	11	10	9	9	9	9	9	8	8
3006	Placebo	10	10	10	10	10	10	10	10	10	10
3007	Active	4	3	4	4	4	5	4	4	5	4
3008	Active	9	8	7	7	6	7	8	7	7	7
3009	Placebo	15	15	14	14	14	12	14	14	14	14
3010	Placebo	5	7	6	6	6	5	4	5	6	6
3011	Active	6	6	7	6	6	6	6	6	6	6
3012	Placebo	14	14	14	14	14	14	14	14	14	14
3013	Active	14	15	14	15	15	15	15	15	15	15
3014	Active	12	12	12	12	12	12	12	12	12	12
3015	Active	22	20	22	22	22	20	22	22	21	22
3016	Placebo	9	9	9	9	9	9	10	9	9	9
3017	Placebo	10	10	10	10	10	10	10	10	10	10
3018	Placebo	15	15	15	15	15	15	15	15	15	15
3019	Active	10	10	10	10	10	10	10	10	10	10
3020	Placebo	17	17	17	17	17	17	17	16	17	17
3021	Active	14	15	15	14	14	14	14	14	14	14
3022	Placebo	.	.	.	.	.	.	.	.	.	.
3023	Active	10	10	10	10	8	8	9	9	7	7
3024	Placebo	18	18	18	18	18	18	18	18	18	18
3025	Placebo	10	10	10	10	10	10	10	10	10	10
3026	Placebo	12	12	10	11	11	11	11	12	12	11
3027	Placebo	15	15	15	15	15	15	14	14	14	13
3028	Active	20	19	20	18	20	20	18	18	18	18
3029	Active	15	15	15	15	15	13	13	13	13	13
3030	Active	19	19	19	19	18	19	19	18	18	18
3031	Active	10	10	10	10	10	10	10	10	10	10

**CONFIDENTIAL**

**Listing 5: Self Reported Smoking**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")

on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

Subject ID	Group	Week 21	Week 22	Week 23	Week 24	Week 25	Week 26	Week 27	Week 28	Week 29	Week 30
3032	Active	26	26	26	25	25	25	25	25	25	24
3033	Placebo	10	10	10	10	10	10	10	10	10	10
3034	Active	10	10	10	9	9	9	9	8	8	8
3035	Placebo	14	13	14	13	10	10	7	7	7	7
3036	Placebo	9	9	10	10	10	10	10	10	10	10
3037	Placebo	7	7	7	7	7	7	7	6	6	6
3038	Active	9	10	10	10	0	0	0	0	0	0
3039	Placebo	7	7	7	7	7	7	6	6	7	7
3040	Active	20	20	20	20	20	20	19	20	20	20
3041	Placebo	15	14	14	14	14	14	12	13	14	13
3042	Active	14	14	15	14	14	14	14	15	15	14
3043	Placebo	6	6	7	7	7	7	7	7	7	6
3044	Active	7	7	7	7	7	7	6	6	6	6
3045	Active	8	9	9	9	10	10	10	9	9	9
3046	Placebo	18	16	18	16	16	16	15	15	16	18
3047	Active	10	10	10	10	10	10	10	9	9	10
3048	Placebo	7	6	6	7	7	7	7	7	6	5
3049	Placebo	11	12	10	11	10	10	11	10	11	10
3050	Active	9	9	8	7	7	7	7	7	5	5

**CONFIDENTIAL**

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**Average number of Cigarettes per day  
(Serbia)**

Subject ID	Group	Week 31	Week 32	Week 33	Week 34	Week 35	Week 36	Week 37	Week 38	Week 39	Week 40
1001	Placebo	.	.	.	.	.	.	.	.	.	.
1002	Placebo	12	20	21	20	10	9	10	10	10	10
1003	Active	.	.	.	.	.	.	.	.	.	.
1004	Active	.	.	.	.	.	.	.	.	.	.
1005	Active	10	12	10	15	12	10	10	8	8	6
1006	Placebo	.	.	.	.	.	.	.	.	.	.
1007	Active	.	.	.	.	.	.	.	.	.	.
1008	Active	20	20	20	20	20	20	15	15	15	15
1009	Placebo	15	15	15	15	15	15	12	10	10	12
1010	Placebo	.	.	.	.	.	.	.	.	.	.
1011	Active	.	.	.	.	.	.	.	.	.	.
1012	Placebo	.	.	.	.	.	.	.	.	.	.
1013	Active	.	.	.	.	.	.	.	.	.	.
1014	Active	.	.	.	.	.	.	.	.	.	.
1015	Active	.	.	.	.	.	.	.	.	.	.
1016	Placebo	7	8	6	5	6	4	6	6	5	5
1017	Placebo	.	.	.	.	.	.	.	.	.	.
1018	Placebo	.	.	.	.	.	.	.	.	.	.
1019	Active	.	.	.	.	.	.	.	.	.	.
1020	Placebo	.	.	.	.	.	.	.	.	.	.
1021	Active	.	.	.	.	.	.	.	.	.	.
1022	Placebo	.	.	.	.	.	.	.	.	.	.
1023	Active	6	6	8	8	5	6	20	20	20	20
1024	Placebo	.	.	.	.	.	.	.	.	.	.
1025	Placebo	.	.	.	.	.	.	.	.	.	.
1026	Placebo	.	.	.	.	.	.	.	.	.	.
1027	Placebo	.	.	.	.	.	.	.	.	.	.
1028	Active	.	.	.	.	.	.	.	.	.	.
1029	Active	.	.	.	.	.	.	.	.	.	.
1030	Active	9	5	7	10	10	5	6	6	6	6
1031	Active	.	.	.	.	.	.	.	.	.	.
1032	Active	.	.	.	.	.	.	.	.	.	.
1033	Placebo	.	.	.	.	.	.	.	.	.	.
1034	Active	.	.	.	.	.	.	.	.	.	.
1035	Placebo	.	.	.	.	.	.	.	.	.	.
1036	Placebo	.	.	.	.	.	.	.	.	.	.
1037	Placebo	8	8	8	8	8	8	10	8	7	7
1038	Active	0	0	0	0	0	0	0	0	0	0
1039	Placebo	.	.	.	.	.	.	.	.	.	.
1040	Active	.	.	.	.	.	.	.	.	.	.
1041	Placebo	.	.	.	.	.	.	.	.	.	.
1042	Active	.	.	.	.	.	.	.	.	.	.
1043	Placebo	.	.	.	.	.	.	.	.	.	.
1044	Active	.	.	.	.	.	.	.	.	.	.
1045	Active	.	.	.	.	.	.	.	.	.	.
1046	Placebo	.	.	.	.	.	.	.	.	.	.
1047	Active	.	.	.	.	.	.	.	.	.	.
1048	Placebo	.	.	.	.	.	.	.	.	.	.
1049	Placebo	.	.	.	.	.	.	.	.	.	.
1050	Active	.	.	.	.	.	.	.	.	.	.

**CONFIDENTIAL**

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**Average number of Cigarettes per day  
(Serbia)**

Subject ID	Group	Week 31	Week 32	Week 33	Week 34	Week 35	Week 36	Week 37	Week 38	Week 39	Week 40
1205	Placebo	8	8	8	10	10	9	6	7	6	7
1206	Placebo	.	.	.	.	.	.	.	.	.	.
1207	Active	.	.	.	.	.	.	.	.	.	.
1208	Active	.	.	.	.	.	.	.	.	.	.
1209	Active	.	.	.	.	.	.	.	.	.	.
1210	Placebo	8	7	8	5	8	6	7	6	5	5
1211	Active	.	.	.	.	.	.	.	.	.	.
1212	Active	5	7	7	6	6	6	6	5	5	6
1213	Placebo	.	.	.	.	.	.	.	.	.	.
1214	Placebo	20	15	12	12	15	10	10	12	10	15
1215	Active	.	.	.	.	.	.	.	.	.	.
1216	Placebo	8	8	7	7	7	6	7	6	6	5
1217	Active	.	.	.	.	.	.	.	.	.	.
1218	Active	.	.	.	.	.	.	.	.	.	.
1219	Active	.	.	.	.	.	.	.	.	.	.
1220	Placebo	10	10	10	10	10	10	10	10	10	10
1221	Placebo	.	.	.	.	.	.	.	.	.	.
1222	Placebo	.	.	.	.	.	.	.	.	.	.
1223	Active	.	.	.	.	.	.	.	.	.	.
1224	Placebo	15	20	25	25	25	25	.	.	.	.
1225	Active	.	.	.	.	.	.	.	.	.	.
1226	Placebo	5	5	5	5	5	5	7	7	7	7
1227	Active	.	.	.	.	.	.	.	.	.	.
1228	Placebo	.	.	.	.	.	.	.	.	.	.
1229	Placebo	.	.	.	.	.	.	.	.	.	.
1230	Placebo	9	9	10	12	12	12	12	12	12	13
1231	Placebo	.	.	.	.	.	.	.	.	.	.
1232	Active	.	.	.	.	.	.	.	.	.	.
1233	Active	7	8	6	8	8	12	11	8	10	10
1234	Active	.	.	.	.	.	.	.	.	.	.
1235	Active	2	2	2	2	1	1	.	.	.	.
1236	Active	.	.	.	.	.	.	.	.	.	.
1237	Placebo	15	15	15	15	15	15	15	13	15	15
1238	Active	.	.	.	.	.	.	.	.	.	.
1239	Placebo	10	10	10	10	10	10	10	9	10	7
1240	Placebo	9	9	9	9	9	9	6	5	2	5
1241	Placebo	.	.	.	.	.	.	.	.	.	.
1242	Active	9	9	9	9	9	9	7	10	8	7
1243	Placebo	6	6	6	6	6	6	5	5	5	5
1244	Active	6	6	6	6	6	6	5	6	5	4
1245	Placebo	6	6	6	6	6	6	6	4	4	3
1246	Active	0	0	0	0	0	0	0	0	0	0
1247	Placebo	15	14	14	15	15	15	15	18	15	15
1325	Placebo	0	0	0	0	0	0	0	0	0	0
1326	Placebo	10	9	9	7	9	9	9	9	6	8
1327	Active	.	.	.	.	.	.	.	.	.	.
1328	Active	0	0	0	0	0	0	0	0	0	0
1329	Active	8	8	10	10	9	10	10	10	7	7
1330	Placebo	9	9	8	10	10	10	8	8	5	5
1331	Active	5	5	3	2	2	0	0	0	0	0

**CONFIDENTIAL**

**Listing 5: Self Reported Smoking**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

Subject ID	Group	Week 31	Week 32	Week 33	Week 34	Week 35	Week 36	Week 37	Week 38	Week 39	Week 40
1332	Active	10	10	10	10	14	14	10	10	10	10
1333	Placebo	9	9	9	6	6	10	10	8	8	8
1334	Placebo	15	17	15	15	18	18	18	15	16	16
1335	Active	10	10	10	10	10	10	8	8	8	8
1336	Placebo	8	10	10	8	8	8	8	8	8	8
1337	Active	10	5	6	8	5	4	9	7	9	8
1338	Active	8	8	3	6	4	6	3	3	2	2
1339	Active	11	10	7	7	11	11	10	10	7	9
1340	Placebo	15	15	15	15	15	15	15	12	12	15
1341	Placebo	8	8	8	10	10	10	8	8	8	8
1342	Placebo	.	.	.	.	.	.	.	.	.	.
1343	Active	4	2	2	4	1	0	0	0	0	0
1344	Placebo	3	4	2	2	0	1	1	0	1	0
1345	Active	1	0	0	0	0	0	0	0	0	0
1346	Placebo	7	5	5	7	10	10	10	8	6	6
1347	Active	.	.	.	.	.	.	.	.	.	.
1348	Placebo	.	.	.	.	.	.	.	.	.	.
1349	Placebo	.	.	.	.	.	.	.	.	.	.
2001	Placebo	9	9	9	9	8	8	7	7	8	7
2002	Placebo	18	18	18	18	18	18	18	18	18	18
2003	Active	10	10	10	9	10	10	10	10	10	10
2004	Active	.	.	.	.	.	.	.	.	.	.
2005	Active	.	.	.	.	.	.	.	.	.	.
2006	Placebo	.	.	.	.	.	.	.	.	.	.
2007	Active	.	.	.	.	.	.	.	.	.	.
2008	Active	.	.	.	.	.	.	.	.	.	.
2009	Placebo	.	.	.	.	.	.	.	.	.	.
2010	Placebo	15	15	12	10	10	8	10	10	10	15
2011	Active	.	.	.	.	.	.	.	.	.	.
2012	Placebo	.	.	.	.	.	.	.	.	.	.
2013	Active	.	.	.	.	.	.	.	.	.	.
2014	Active	.	.	.	.	.	.	.	.	.	.
2015	Active	.	.	.	.	.	.	.	.	.	.
2016	Placebo	3	2	2	0	0	2	1	1	1	0
2017	Placebo	.	.	.	.	.	.	.	.	.	.
2018	Placebo	.	.	.	.	.	.	.	.	.	.
2019	Active	.	.	.	.	.	.	.	.	.	.
2020	Placebo	.	.	.	.	.	.	.	.	.	.
2021	Active	15	15	15	14	15	15	15	15	15	15
2022	Placebo	18	20	18	18	20	18	20	25	25	25
2023	Active	.	.	.	.	.	.	.	.	.	.
2024	Placebo	.	.	.	.	.	.	.	.	.	.
2025	Placebo	9	10	10	9	9	10	10	10	10	10
2026	Placebo	7	8	6	7	7	8	7	7	6	6
2027	Placebo	4	5	5	4	4	4	5	5	4	5
2028	Active	0	2	0	0	1	0	0	2	2	0
2029	Active	10	10	10	10	10	10	10	10	10	10
2030	Active	13	12	12	12	10	10	10	8	8	8
2031	Active	7	7	7	7	7	7	.	.	.	.
2032	Active	15	15	14	15	15	15	15	15	15	15

**CONFIDENTIAL**

**Listing 5: Self Reported Smoking**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

<b>Subject ID</b>	<b>Group</b>	<b>Week 31</b>	<b>Week 32</b>	<b>Week 33</b>	<b>Week 34</b>	<b>Week 35</b>	<b>Week 36</b>	<b>Week 37</b>	<b>Week 38</b>	<b>Week 39</b>	<b>Week 40</b>
2033	Placebo	10	10	10	10	10	10	10	10	10	10
2034	Active	.	.	.	.	.	.	.	.	.	.
2035	Placebo	27	25	25	25	22	26	26	26	26	26
2036	Placebo	12	12	12	12	10	12	12	12	12	12
2037	Placebo	.	.	.	.	.	.	.	.	.	.
2038	Active	.	.	.	.	.	.	.	.	.	.
2039	Placebo	9	9	9	9	9	9	9	9	10	10
2040	Active	.	.	.	.	.	.	.	.	.	.
2041	Placebo	.	.	.	.	.	.	.	.	.	.
2042	Active	10	10	10	10	10	10	10	10	10	10
2043	Placebo	.	.	.	.	.	.	.	.	.	.
2044	Active	15	15	15	15	15	15	15	15	14	14
2045	Active	14	14	15	14	14	14	14	14	14	14
2046	Placebo	.	.	.	.	.	.	.	.	.	.
2047	Active	3	3	2	0	2	0	0	1	1	1
2048	Placebo	4	0	0	0	0	0	0	0	0	0
2049	Placebo	8	8	8	8	8	8	8	8	8	8
2050	Active	10	10	10	10	10	10	10	10	10	10
2205	Active	13	13	12	13	13	13	12	12	10	10
2206	Placebo	10	10	9	9	10	10	10	10	10	11
2207	Placebo	12	12	11	12	10	10	10	11	9	10
2208	Active	11	11	10	10	10	9	9	9	12	12
2209	Active	10	9	9	10	9	10	9	9	9	8
2210	Placebo	0	0	0	0	0	0	0	0	0	0
2211	Placebo	4	5	10	9	7	9	12	9	10	10
2212	Placebo	13	12	13	13	12	12	10	8	8	10
2213	Active	11	11	11	12	10	10	10	10	10	10
2214	Active	12	10	10	10	12	12	12	10	10	10
2215	Active	10	10	10	10	10	10	10	12	13	15
2216	Placebo	18	19	18	18	17	18	18	18	17	18
2217	Active	10	10	8	8	10	8	6	3	2	1
2218	Placebo	10	10	10	9	9	10	10	9	9	7
2219	Active	10	10	10	11	10	10	10	8	9	9
2220	Placebo	5	5	5	5	6	6	10	10	9	9
2221	Placebo	11	10	10	9	9	9	9	8	6	5
2222	Active	6	6	7	8	6	6	6	6	5	6
2223	Placebo	5	5	6	8	5	5	5	5	4	5
2224	Placebo	11	9	9	9	9	10	10	10	10	10
2225	Placebo	8	9	8	7	9	8	8	9	7	8
2226	Active	18	18	18	18	18	18	18	20	20	18
2227	Active	8	10	9	10	8	8	8	7	8	10
2228	Active	9	8	8	9	9	9	9	10	8	8
2229	Placebo	9	10	10	9	9	9	9	11	12	8
2230	Active	7	9	9	6	6	6	6	6	7	7
2231	Active	7	7	7	6	6	7	8	7	7	7
2232	Placebo	10	9	9	10	9	9	9	8	9	8
2233	Placebo	18	16	16	18	17	15	15	18	18	18
2234	Active	25	25	25	22	22	24	25	30	30	26
2235	Placebo	14	15	15	13	12	12	12	12	11	11
2236	Placebo	6	6	7	7	6	6	7	8	7	6

**CONFIDENTIAL**

**Listing 5: Self Reported Smoking**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

Subject ID	Group	Week 31	Week 32	Week 33	Week 34	Week 35	Week 36	Week 37	Week 38	Week 39	Week 40
2237	Placebo	10	9	9	10	10	10	9	9	9	8
2238	Active	5	5	5	5	5	5	5	6	6	5
2239	Active	13	13	14	15	13	13	12	12	13	12
2240	Active	9	9	10	6	6	8	10	16	8	8
2241	Active	12	13	13	15	15	15	14	13	13	12
2242	Active	3	2	0	0	0	0	0	0	0	0
2243	Placebo	8	8	5	7	7	7	8	8	7	7
2244	Placebo	8	8	10	10	9	8	8	7	7	7
2245	Active	0	0	0	0	0	0	0	0	0	0
2246	Placebo	10	10	10	10	10	10	10	10	10	10
2247	Active	5	5	5	5	5	5	5	5	5	5
2248	Active	7	6	6	8	7	7	10	10	12	15
2249	Placebo	12	10	10	12	10	10	10	10	10	8
2250	Placebo	5	5	5	5	5	5	5	6	6	5
2251	Active	10	10	10	10	10	10	10	9	9	9
2252	Placebo	13	12	12	12	12	12	12	8	8	10
2253	Active	7	9	9	7	8	8	8	7	9	7
2254	Placebo	15	14	15	15	15	15	16	14	14	16
2255	Active	.	.	.	.	.	.	.	.	.	.
2256	Placebo	10	9	9	9	8	9	7	7	6	0
2257	Active	0	0	0	0	0	0	0	0	0	0
2258	Placebo	5	5	7	5	2	3	3	2	4	5
2259	Placebo	3	1	0	0	0	0	0	0	0	0
2260	Placebo	10	10	8	8	10	10	8	8	8	10
2261	Active	.	.	.	.	.	.	.	.	.	.
2262	Active	0	0	0	0	0	0	0	0	0	0
2263	Placebo	.	.	.	.	.	.	.	.	.	.
2264	Active	.	.	.	.	.	.	.	.	.	.
2265	Active	16	22	22	18	18	18	18	18	16	15
2266	Active	9	9	8	8	9	9	9	9	8	8
2267	Active	16	16	12	12	16	20	18	18	20	18
2268	Placebo	.	.	.	.	.	.	.	.	.	.
2269	Placebo	.	.	.	.	.	.	.	.	.	.
2270	Placebo	0	0	0	0	0	0	0	0	0	0
2271	Placebo	5	5	5	5	5	5	4	5	5	5
2272	Placebo	.	.	.	.	.	.	.	.	.	.
2273	Active	.	.	.	.	.	.	.	.	.	.
2274	Placebo	10	10	7	7	7	4	4	4	5	15
2275	Active	0	0	0	0	0	0	0	0	0	0
2276	Active	.	.	.	.	.	.	.	.	.	.
2277	Active	0	0	0	0	0	0	0	0	0	0
2278	Active	.	.	.	.	.	.	.	.	.	.
2279	Placebo	10	10	10	15	15	15	20	20	20	20
2280	Placebo	5	5	5	6	6	5	7	7	6	6
2281	Active	.	.	.	.	.	.	.	.	.	.
2282	Placebo	15	14	15	14	14	15	14	14	14	12
2283	Placebo	.	.	.	.	.	.	.	.	.	.
2284	Active	.	.	.	.	.	.	.	.	.	.
2285	Active	.	.	.	.	.	.	.	.	.	.
2286	Placebo	.	.	.	.	.	.	.	.	.	.

**CONFIDENTIAL**

**Listing 5: Self Reported Smoking**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

Subject ID	Group	Week 31	Week 32	Week 33	Week 34	Week 35	Week 36	Week 37	Week 38	Week 39	Week 40
2287	Active	5	5	5	5	5	5	5	5	5	5
2288	Placebo	.	.	.	.	.	.	.	.	.	.
2289	Active	20	20	20	20	20	20	20	20	20	20
2290	Placebo	5	5	5	5	5	5	5	5	5	5
2291	Active	8	10	8	8	10	10	8	8	8	8
2292	Placebo	.	.	.	.	.	.	.	.	.	.
2293	Placebo	10	10	10	7	7	7	7	6	6	7
2294	Active	.	.	.	.	.	.	.	.	.	.
2295	Active	0	0	0	0	0	0	0	0	0	0
2296	Active	0	0	0	0	0	0	0	0	0	0
2297	Placebo	10	10	10	10	8	8	8	8	9	9
2298	Placebo	10	10	10	10	11	9	10	9	10	10
2299	Active	.	.	.	.	.	.	.	.	.	.
2300	Placebo	10	10	10	7	10	10	10	10	10	10
2301	Active	.	.	.	.	.	.	.	.	.	.
2302	Placebo	12	11	11	12	11	13	12	10	11	10
2303	Active	.	.	.	.	.	.	.	.	.	.
2304	Placebo	.	.	.	.	.	.	.	.	.	.
2305	Placebo	0	0	0	0	0	0	0	0	0	0
2306	Active	5	5	5	5	5	5	5	5	5	5
3001	Placebo	8	8	8	8	8	8	8	8	7	7
3002	Placebo	9	8	9	8	9	8	8	8	8	8
3003	Active	14	14	12	8	10	11	9	9	11	10
3004	Active	8	8	7	7	5	5	5	5	4	4
3006	Placebo	10	10	10	10	10	10	10	10	10	10
3007	Active	4	4	4	4	4	4	4	2	2	0
3008	Active	7	7	6	6	7	6	6	7	7	7
3009	Placebo	14	12	12	12	13	14	14	14	15	14
3010	Placebo	4	6	6	5	6	5	8	8	5	6
3011	Active	6	6	6	6	6	4	4	4	4	3
3012	Placebo	14	13	13	12	13	12	12	12	12	12
3013	Active	10	8	2	0	5	5	3	2	0	1
3014	Active	12	12	10	12	11	10	10	10	10	10
3015	Active	22	22	22	22	22	22	22	22	23	22
3016	Placebo	9	9	7	9	9	8	9	9	10	9
3017	Placebo	10	10	9	9	9	10	10	10	10	10
3018	Placebo	15	15	15	15	15	15	15	15	15	15
3019	Active	10	10	9	9	10	10	10	10	9	10
3020	Placebo	16	16	17	15	15	16	16	16	15	15
3021	Active	14	14	12	12	12	12	12	12	12	12
3022	Placebo	.	.	.	.	.	.	.	.	.	.
3023	Active	6	9	8	7	6	6	6	6	6	6
3024	Placebo	18	17	17	20	18	18	18	17	17	18
3025	Placebo	10	12	12	10	12	10	10	10	12	10
3026	Placebo	12	11	11	12	12	11	11	12	12	10
3027	Placebo	10	12	12	10	12	10	10	10	12	10
3028	Active	19	19	19	20	20	18	18	18	18	18
3029	Active	15	15	15	13	13	13	12	14	14	14
3030	Active	18	19	20	19	19	20	17	18	20	18
3031	Active	10	10	9	9	10	10	10	9	10	9

**CONFIDENTIAL**

**Listing 5: Self Reported Smoking**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")

on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

Subject ID	Group	Week 31	Week 32	Week 33	Week 34	Week 35	Week 36	Week 37	Week 38	Week 39	Week 40
3032	Active	25	25	24	24	25	25	25	23	23	24
3033	Placebo	10	10	10	10	10	10	10	9	9	9
3034	Active	8	8	9	9	10	8	8	8	8	8
3035	Placebo	15	15	15	16	16	16	10	10	9	9
3036	Placebo	10	10	10	9	9	10	10	10	9	9
3037	Placebo	6	6	7	7	7	6	6	6	7	7
3038	Active	0	0	0	0	0	0	0	0	0	0
3039	Placebo	6	6	7	6	5	6	6	6	6	7
3040	Active	20	19	19	18	18	18	18	18	18	17
3041	Placebo	15	14	14	14	13	14	14	14	12	13
3042	Active	14	14	14	13	14	15	14	15	15	14
3043	Placebo	6	6	6	6	6	6	5	5	6	5
3044	Active	6	6	5	5	5	5	5	5	6	5
3045	Active	9	8	2	8	8	8	10	10	9	9
3046	Placebo	18	18	17	16	15	15	16	16	15	15
3047	Active	9	9	9	10	10	9	8	10	10	9
3048	Placebo	6	6	6	6	5	5	6	6	6	6
3049	Placebo	10	10	11	10	10	10	10	10	10	10
3050	Active	5	5	5	4	5	4	3	3	3	3

**CONFIDENTIAL**

**Listing 5: Self Reported Smoking**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

Subject ID	Group	Week 41	Week 42	Week 43	Week 44	Week 45	Week 46	Week 47	Week 48
1001	Placebo	.	.	.	.	.	.	.	.
1002	Placebo	10	10	10	12	12	15	15	13
1003	Active	.	.	.	.	.	.	.	.
1004	Active	.	.	.	.	.	.	.	.
1005	Active	6	6	.	.	.	.	.	.
1006	Placebo	.	.	.	.	.	.	.	.
1007	Active	.	.	.	.	.	.	.	.
1008	Active	15	15	15	15	15	15	15	15
1009	Placebo	12	10	15	15	15	15	15	15
1010	Placebo	.	.	.	.	.	.	.	.
1011	Active	.	.	.	.	.	.	.	.
1012	Placebo	.	.	.	.	.	.	.	.
1013	Active	.	.	.	.	.	.	.	.
1014	Active	.	.	.	.	.	.	.	.
1015	Active	.	.	.	.	.	.	.	.
1016	Placebo	5	5	6	5	5	7	4	9
1017	Placebo	.	.	.	.	.	.	.	.
1018	Placebo	.	.	.	.	.	.	.	.
1019	Active	.	.	.	.	.	.	.	.
1020	Placebo	.	.	.	.	.	.	.	.
1021	Active	.	.	.	.	.	.	.	.
1022	Placebo	.	.	.	.	.	.	.	.
1023	Active	20	20	20	15	15	15	15	15
1024	Placebo	.	.	.	.	.	.	.	.
1025	Placebo	.	.	.	.	.	.	.	.
1026	Placebo	.	.	.	.	.	.	.	.
1027	Placebo	.	.	.	.	.	.	.	.
1028	Active	.	.	.	.	.	.	.	.
1029	Active	.	.	.	.	.	.	.	.
1030	Active	6	6	6	8	8	6	7	6
1031	Active	.	.	.	.	.	.	.	.
1032	Active	.	.	.	.	.	.	.	.
1033	Placebo	.	.	.	.	.	.	.	.
1034	Active	.	.	.	.	.	.	.	.
1035	Placebo	.	.	.	.	.	.	.	.
1036	Placebo	.	.	.	.	.	.	.	.
1037	Placebo	7	8	8	10	10	8	8	0
1038	Active	0	0	0	0	0	0	0	0
1039	Placebo	.	.	.	.	.	.	.	.
1040	Active	.	.	.	.	.	.	.	.
1041	Placebo	.	.	.	.	.	.	.	.
1042	Active	.	.	.	.	.	.	.	.
1043	Placebo	.	.	.	.	.	.	.	.
1044	Active	.	.	.	.	.	.	.	.
1045	Active	.	.	.	.	.	.	.	.
1046	Placebo	.	.	.	.	.	.	.	.
1047	Active	.	.	.	.	.	.	.	.
1048	Placebo	.	.	.	.	.	.	.	.
1049	Placebo	.	.	.	.	.	.	.	.
1050	Active	.	.	.	.	.	.	.	.

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**Listing 5: Self Reported Smoking**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

Subject ID	Group	Week 41	Week 42	Week 43	Week 44	Week 45	Week 46	Week 47	Week 48
1205	Placebo	7	6	8	8	8	8	8	8
1206	Placebo	.	.	.	.	.	.	.	.
1207	Active	.	.	.	.	.	.	.	.
1208	Active	.	.	.	.	.	.	.	.
1209	Active	.	.	.	.	.	.	.	.
1210	Placebo	5	5	7	8	8	7	7	8
1211	Active	.	.	.	.	.	.	.	.
1212	Active	6	6	7	6	6	6	6	6
1213	Placebo	.	.	.	.	.	.	.	.
1214	Placebo	12	12	.	.	.	.	.	.
1215	Active	.	.	.	.	.	.	.	.
1216	Placebo	5	5	5	6	5	6	6	5
1217	Active	.	.	.	.	.	.	.	.
1218	Active	.	.	.	.	.	.	.	.
1219	Active	.	.	.	.	.	.	.	.
1220	Placebo	10	10	10	13	12	11	12	12
1221	Placebo	.	.	.	.	.	.	.	.
1222	Placebo	.	.	.	.	.	.	.	.
1223	Active	.	.	.	.	.	.	.	.
1224	Placebo	.	.	.	.	.	.	.	.
1225	Active	.	.	.	.	.	.	.	.
1226	Placebo	7	7	7	7	7	7	7	7
1227	Active	.	.	.	.	.	.	.	.
1228	Placebo	.	.	.	.	.	.	.	.
1229	Placebo	.	.	.	.	.	.	.	.
1230	Placebo	12	12	12	15	14	15	15	14
1231	Placebo	.	.	.	.	.	.	.	.
1232	Active	.	.	.	.	.	.	.	.
1233	Active	9	10	10	7	7	5	8	7
1234	Active	.	.	.	.	.	.	.	.
1235	Active	.	.	.	.	.	.	.	.
1236	Active	.	.	.	.	.	.	.	.
1237	Placebo	12	13	13	13	15	14	13	13
1238	Active	.	.	.	.	.	.	.	.
1239	Placebo	10	10	12	10	12	10	10	10
1240	Placebo	4	4	5	5	4	5	5	5
1241	Placebo	.	.	.	.	.	.	.	.
1242	Active	9	7	10	10	10	10	10	10
1243	Placebo	5	5	10	8	10	5	7	8
1244	Active	4	5	6	6	7	6	5	6
1245	Placebo	2	3	3	3	4	4	3	3
1246	Active	0	0	0	0	0	0	0	0
1247	Placebo	17	18	.	.	.	.	.	.
1325	Placebo	0	0	0	0	0	0	0	0
1326	Placebo	9	8	7	7	9	7	8	8
1327	Active	.	.	.	.	.	.	.	.
1328	Active	0	0	0	0	0	0	0	0
1329	Active	7	9	7	7	8	7	8	8
1330	Placebo	7	8	8	7	7	8	9	7
1331	Active	0	0	0	0	0	0	0	0

**CONFIDENTIAL**

**Listing 5: Self Reported Smoking**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

Subject ID	Group	Week 41	Week 42	Week 43	Week 44	Week 45	Week 46	Week 47	Week 48
1332	Active	8	8	10	10	8	9	9	10
1333	Placebo	7	8	8	10	3	5	9	8
1334	Placebo	15	15	15	15	15	15	15	15
1335	Active	8	8	8	8	10	7	10	8
1336	Placebo	8	8	10	10	7	7	10	10
1337	Active	8	9	9	7	8	6	8	9
1338	Active	2	1	0	0	0	0	0	0
1339	Active	9	9	10	8	8	6	10	9
1340	Placebo	15	15	14	15	14	14	15	14
1341	Placebo	8	8	8	6	6	8	5	8
1342	Placebo	.	.	.	.	.	.	.	.
1343	Active	0	0	0	0	0	0	0	0
1344	Placebo	0	0	0	0	0	0	0	0
1345	Active	0	0	0	0	0	0	0	0
1346	Placebo	6	6	6	8	8	6	6	6
1347	Active	.	.	.	.	.	.	.	.
1348	Placebo	.	.	.	.	.	.	.	.
1349	Placebo	.	.	.	.	.	.	.	.
2001	Placebo	7	7	8	7	8	7	7	7
2002	Placebo	18	18	18	18	18	18	18	18
2003	Active	10	10	10	10	12	12	10	12
2004	Active	.	.	.	.	.	.	.	.
2005	Active	.	.	.	.	.	.	.	.
2006	Placebo	.	.	.	.	.	.	.	.
2007	Active	.	.	.	.	.	.	.	.
2008	Active	.	.	.	.	.	.	.	.
2009	Placebo	.	.	.	.	.	.	.	.
2010	Placebo	12	12	15	15	15	15	15	15
2011	Active	.	.	.	.	.	.	.	.
2012	Placebo	.	.	.	.	.	.	.	.
2013	Active	.	.	.	.	.	.	.	.
2014	Active	.	.	.	.	.	.	.	.
2015	Active	.	.	.	.	.	.	.	.
2016	Placebo	1	0	0	0	0	0	0	0
2017	Placebo	.	.	.	.	.	.	.	.
2018	Placebo	.	.	.	.	.	.	.	.
2019	Active	.	.	.	.	.	.	.	.
2020	Placebo	.	.	.	.	.	.	.	.
2021	Active	15	15	15	18	18	18	20	20
2022	Placebo	25	25	30	28	30	30	30	30
2023	Active	.	.	.	.	.	.	.	.
2024	Placebo	.	.	.	.	.	.	.	.
2025	Placebo	10	10	10	10	10	10	10	10
2026	Placebo	6	7	1	0	0	0	0	0
2027	Placebo	4	5	5	5	4	4	5	4
2028	Active	1	0	0	0	0	0	0	0
2029	Active	10	10	10	10	10	10	10	10
2030	Active	10	10	8	6	5	5	5	5
2031	Active	.	.	.	.	.	.	.	.
2032	Active	15	15	15	15	15	15	15	15

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**Listing 5: Self Reported Smoking**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

<b>Subject ID</b>	<b>Group</b>	<b>Week 41</b>	<b>Week 42</b>	<b>Week 43</b>	<b>Week 44</b>	<b>Week 45</b>	<b>Week 46</b>	<b>Week 47</b>	<b>Week 48</b>
2033	Placebo	10	10	10	10	10	10	10	10
2034	Active	.	.	.	.	.	.	.	.
2035	Placebo	26	27	26	26	26	25	25	25
2036	Placebo	12	12	12	10	12	12	12	12
2037	Placebo	.	.	.	.	.	.	.	.
2038	Active	.	.	.	.	.	.	.	.
2039	Placebo	10	10	10	10	10	10	10	10
2040	Active	.	.	.	.	.	.	.	.
2041	Placebo	.	.	.	.	.	.	.	.
2042	Active	10	10	10	10	10	10	10	10
2043	Placebo	.	.	.	.	.	.	.	.
2044	Active	15	15	15	13	15	15	15	15
2045	Active	14	14	14	14	14	15	15	15
2046	Placebo	.	.	.	.	.	.	.	.
2047	Active	0	0	2	0	0	0	0	0
2048	Placebo	0	0	0	0	0	0	0	0
2049	Placebo	8	8	8	8	8	10	8	10
2050	Active	10	10	10	10	9	10	10	10
2205	Active	10	9	10	10	9	9	10	9
2206	Placebo	10	10	10	10	10	10	9	10
2207	Placebo	9	9	9	10	10	9	9	9
2208	Active	12	10	10	10	8	10	9	9
2209	Active	8	8	8	8	9	9	8	7
2210	Placebo	0	0	0	0	0	0	0	0
2211	Placebo	12	10	10	10	11	12	13	15
2212	Placebo	9	9	9	10	10	9	9	8
2213	Active	10	10	6	7	7	5	5	5
2214	Active	11	11	12	12	10	10	9	10
2215	Active	15	14	13	13	10	10	12	12
2216	Placebo	18	16	14	15	13	15	15	14
2217	Active	0	0	0	0	0	0	0	0
2218	Placebo	10	10	10	10	9	9	10	9
2219	Active	10	8	9	9	9	8	9	8
2220	Placebo	9	9	8	8	8	8	7	7
2221	Placebo	6	5	5	0	0	0	0	0
2222	Active	6	6	6	7	7	3	5	6
2223	Placebo	4	4	4	4	5	5	5	5
2224	Placebo	12	10	10	10	10	10	10	10
2225	Placebo	7	9	8	8	7	8	7	7
2226	Active	20	17	18	17	17	16	17	16
2227	Active	8	7	8	8	9	9	9	9
2228	Active	9	9	8	8	8	7	8	7
2229	Placebo	8	9	9	9	9	9	8	8
2230	Active	6	8	8	8	7	9	9	9
2231	Active	7	8	7	7	7	7	7	7
2232	Placebo	6	6	6	7	7	8	6	6
2233	Placebo	16	14	14	12	12	12	12	12
2234	Active	26	30	28	28	25	25	28	25
2235	Placebo	14	14	12	11	12	10	12	11
2236	Placebo	6	5	4	3	1	1	0	0

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**Listing 5: Self Reported Smoking**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")

on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

Subject ID	Group	Week 41	Week 42	Week 43	Week 44	Week 45	Week 46	Week 47	Week 48
2237	Placebo	8	8	8	9	9	8	8	8
2238	Active	6	6	3	1	1	0	0	0
2239	Active	12	12	12	11	10	11	10	9
2240	Active	7	8	9	9	8	8	8	9
2241	Active	12	13	11	11	12	10	10	10
2242	Active	0	0	0	0	0	0	0	0
2243	Placebo	7	5	10	9	8	6	6	6
2244	Placebo	7	7	7	7	8	7	8	9
2245	Active	0	0	0	0	0	0	0	0
2246	Placebo	10	10	10	10	10	10	10	10
2247	Active	5	5	5	5	5	5	5	5
2248	Active	15	15	12	12	10	10	10	10
2249	Placebo	8	9	9	9	8	8	8	8
2250	Placebo	4	4	4	3	2	1	0	0
2251	Active	9	9	10	9	9	10	10	9
2252	Placebo	10	10	10	9	9	9	9	10
2253	Active	7	8	8	7	9	7	8	7
2254	Placebo	14	16	15	14	13	14	14	14
2255	Active	.	.	.	.	.	.	.	.
2256	Placebo	0	0	0	0	0	0	0	0
2257	Active	0	0	0	0	0	0	0	0
2258	Placebo	1	4	1	1	0	0	0	0
2259	Placebo	0	0	0	0	0	0	0	0
2260	Placebo	10	8	8	10	10	8	8	10
2261	Active	.	.	.	.	.	.	.	.
2262	Active	0	0	0	0	0	0	0	0
2263	Placebo	.	.	.	.	.	.	.	.
2264	Active	.	.	.	.	.	.	.	.
2265	Active	15	14	14	14	15	18	15	15
2266	Active	7	7	7	7	7	7	10	7
2267	Active	18	18	18	16	15	16	15	16
2268	Placebo	.	.	.	.	.	.	.	.
2269	Placebo	.	.	.	.	.	.	.	.
2270	Placebo	0	0	0	0	0	0	0	0
2271	Placebo	5	5	5	5	5	5	5	5
2272	Placebo	.	.	.	.	.	.	.	.
2273	Active	.	.	.	.	.	.	.	.
2274	Placebo	15	15	18	15	15	15	15	15
2275	Active	0	0	0	0	0	0	0	0
2276	Active	.	.	.	.	.	.	.	.
2277	Active	0	0	0	0	0	0	0	0
2278	Active	.	.	.	.	.	.	.	.
2279	Placebo	20	20	20	20	15	15	15	15
2280	Placebo	5	9	10	7	7	8	7	8
2281	Active	.	.	.	.	.	.	.	.
2282	Placebo	14	12	12	13	10	10	10	12
2283	Placebo	.	.	.	.	.	.	.	.
2284	Active	.	.	.	.	.	.	.	.
2285	Active	.	.	.	.	.	.	.	.
2286	Placebo	.	.	.	.	.	.	.	.

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**Listing 5: Self Reported Smoking**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

Subject ID	Group	Week 41	Week 42	Week 43	Week 44	Week 45	Week 46	Week 47	Week 48
2287	Active	5	5	.	.	.	.	.	.
2288	Placebo	.	.	.	.	.	.	.	.
2289	Active	20	20	.	.	.	.	.	.
2290	Placebo	5	5	.	.	.	.	.	.
2291	Active	8	8	.	.	.	.	.	.
2292	Placebo	.	.	.	.	.	.	.	.
2293	Placebo	5	7	.	.	.	.	.	.
2294	Active	.	.	.	.	.	.	.	.
2295	Active	0	0	0	0	0	0	0	0
2296	Active	0	0	0	0	0	0	0	0
2297	Placebo	8	8	.	.	.	.	.	.
2298	Placebo	9	9	.	.	.	.	.	.
2299	Active	.	.	.	.	.	.	.	.
2300	Placebo	10	10	12	10	10	7	10	10
2301	Active	.	.	.	.	.	.	.	.
2302	Placebo	11	13	13	11	13	10	11	11
2303	Active	.	.	.	.	.	.	.	.
2304	Placebo	.	.	.	.	.	.	.	.
2305	Placebo	0	0	0	0	0	0	0	0
2306	Active	5	5	.	.	.	.	.	.
3001	Placebo	7	7	6	5	5	7	6	5
3002	Placebo	8	8	7	7	5	6	6	6
3003	Active	8	10	14	12	12	10	11	10
3004	Active	3	2	2	1	1	1	1	0
3006	Placebo	10	10	10	10	10	9	9	9
3007	Active	0	1	0	0	0	0	0	0
3008	Active	6	6	6	7	5	5	6	5
3009	Placebo	14	15	15	15	14	14	14	14
3010	Placebo	6	3	3	3	4	3	3	3
3011	Active	3	3	2	2	0	0	0	0
3012	Placebo	12	12	12	12	12	11	11	12
3013	Active	0	0	0	0	0	0	0	0
3014	Active	10	10	10	10	10	10	10	10
3015	Active	23	20	20	20	22	25	25	22
3016	Placebo	9	9	8	8	8	9	9	9
3017	Placebo	10	9	10	9	9	9	9	9
3018	Placebo	15	15	15	14	14	14	14	12
3019	Active	9	9	9	8	9	8	8	8
3020	Placebo	16	16	16	15	14	16	16	16
3021	Active	12	12	12	12	12	10	10	10
3022	Placebo	.	.	.	.	.	.	.	.
3023	Active	5	5	5	6	5	6	5	5
3024	Placebo	16	16	16	17	16	15	15	15
3025	Placebo	10	10	10	10	9	10	10	10
3026	Placebo	10	10	11	12	10	12	10	10
3027	Placebo	10	10	10	10	12	12	14	15
3028	Active	19	20	19	18	18	18	20	20
3029	Active	14	14	13	12	12	13	12	12
3030	Active	18	20	20	19	19	20	19	19
3031	Active	10	10	10	9	10	9	8	8

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**Listing 5: Self Reported Smoking**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(Serbia)**

<b>Subject ID</b>	<b>Group</b>	<b>Week 41</b>	<b>Week 42</b>	<b>Week 43</b>	<b>Week 44</b>	<b>Week 45</b>	<b>Week 46</b>	<b>Week 47</b>	<b>Week 48</b>
3032	Active	23	23	23	22	23	22	20	25
3033	Placebo	10	10	10	10	10	10	10	10
3034	Active	8	8	5	5	5	4	4	3
3035	Placebo	9	9	18	18	17	18	18	18
3036	Placebo	9	8	11	10	9	9	9	8
3037	Placebo	6	6	7	7	6	6	6	6
3038	Active	0	0	0	0	0	0	0	0
3039	Placebo	6	6	4	4	4	3	5	3
3040	Active	19	18	18	20	20	21	21	21
3041	Placebo	10	14	14	12	12	13	13	13
3042	Active	15	15	14	14	14	13	13	14
3043	Placebo	6	5	6	6	7	7	5	5
3044	Active	6	5	6	6	5	5	5	5
3045	Active	10	8	9	8	8	8	8	9
3046	Placebo	18	15	15	15	18	18	17	10
3047	Active	8	9	9	8	9	9	8	7
3048	Placebo	6	6	6	6	7	7	7	6
3049	Placebo	10	9	8	10	12	12	10	9
3050	Active	3	3	2	2	1	1	0	0

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**Listing 6: User Diary**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(USA)**

Subject ID	Group	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10
R1001	Active	10.00	10.00	10.00	8.00	7.00	4.00	0.00	0.00	0.00	2.00
R1002	Placebo	5.00	4.00	4.00	2.00	4.00	2.00	2.00	2.90	3.00	6.00
R1003	Active	7.00	.	.	.	.	.	.	.	.	.
R1004	Placebo	10.00	10.00	7.00	6.00	5.00	.	2.00	0.00	2.00	4.00
R1005	Active	20.00	12.00	12.00	16.00	6.00	5.00	10.00	5.00	.	5.00
R1006	Placebo	15.00	15.00	10.00	10.00	12.00	.	10.00	10.00	10.00	10.00
R1007	Active	8.00	5.00	10.00	5.00	3.00	0.00	0.00	0.00	0.00	0.00
R1008	Placebo	18.00	14.00	10.00	5.00	4.00	10.00	8.00	10.00	15.00	.
R1009	Active	15.00	15.00	12.00	6.00	1.00	5.00	5.00	10.00	10.00	.
R1010	Active	12.00	10.00	8.00	8.00	0.00	0.00	0.00	0.00	0.00	0.00
R1011	Placebo	15.00	10.00	10.00	10.00	15.00	10.00	8.00	8.00	8.00	15.00
R1012	Placebo	10.00	10.00	11.00	4.00	12.00	12.00	10.00	10.00	15.00	20.00
R1013	Placebo	15.00	15.00	15.00	10.00	8.00	6.00	5.00	1.00	4.00	4.00
R1014	Placebo	.	.	.	.	.	.	.	.	.	.
R1015	Active	5.00	4.00	3.00	2.00	1.00	1.00	0.40	0.40	0.40	2.10
R1016	Active	10.00	5.00	3.00	3.00	5.00	3.00	.	2.00	5.00	7.00
R1017	Active	10.00	10.00	5.00	5.00	6.00	6.00	5.00	5.00	5.00	5.00
R1018	Placebo	15.00	15.00	10.00	13.00	15.00	15.00	15.00	4.00	2.00	2.00
R1019	Active	15.00	11.00	9.00	8.00	8.00	8.00	7.00	8.00	6.00	6.00
R1020	Placebo	15.00	10.00	15.00	15.00	0.00	0.00	0.00	0.00	0.00	0.00
R1021	Placebo	10.00	10.00	8.00	8.00	3.00	3.00	3.00	3.00	8.00	3.00
R1022	Active	15.00	10.00	15.00	10.00	.	5.00	5.00	5.00	5.00	4.00
R1023	Placebo	10.00	12.00	9.00	15.00	17.00	18.00	.	.	.	.
R1024	Active	15.00	15.00	15.00	10.00	15.00	.	10.00	10.00	10.00	10.00
R1025	Active	8.00	7.00	15.00	5.00	0.00	0.00	0.00	0.00	0.00	0.00
R1026	Active	15.00	13.00	10.00	10.00	8.00	3.00	6.00	5.00	4.00	10.00
R1027	Placebo	15.00	15.00	.	.	.	.	.	.	.	.
R1028	Placebo	10.00	9.00	7.00	5.00	4.00	1.30	2.00	2.00	4.00	4.00
R1029	Active	4.00	4.00	4.00	4.00	4.00	0.00	.	.	.	.
R1030	Placebo	12.00	10.00	10.00	8.00	0.00	0.00	0.00	10.00	3.00	2.00
R1031	Active	3.00	8.00	2.00	3.00	5.00	5.00	10.00	5.00	5.00	10.00
R1032	Active	8.00	5.00	3.00	1.00	0.40	0.00	0.00	1.00	1.00	0.00
R1033	Placebo	10.00	10.00	7.00	7.00	7.00	7.00	.	.	.	.
R1034	Placebo	6.00	6.00	8.00	6.00	5.00	6.00	8.00	8.00	7.00	6.00
R1035	Active	18.00	19.00	17.00	11.00	10.00	10.00	11.00	12.00	11.00	12.00
R1036	Placebo	15.00	10.00	5.00	1.50	0.00	1.00	0.00	0.00	1.00	0.00
R1037	Active	20.00	20.00	10.00	10.00	5.00	20.00	30.00	30.00	20.00	20.00
R5001	Placebo	15.00	15.00	20.00	12.00	5.00	15.00	15.00	15.00	15.00	10.00
R5002	Active	6.00	6.00	6.00	4.00	0.00	1.00	0.00	0.00	0.00	0.00
R5003	Placebo	20.00	15.00	20.00	15.00	20.00	15.00	12.00	10.00	10.00	10.00
R5004	Active	10.00	10.00	12.00	7.00	4.00	.	15.00	12.00	8.00	8.00
R5005	Placebo	7.00	7.00	8.00	6.00	2.00	.	.	.	.	.
R5006	Active	18.00	18.00	18.00	18.00	18.00	18.00	10.00	12.00	6.00	7.00
R5007	Active	.	.	.	.	.	.	.	.	.	.
R5008	Placebo	15.00	10.00	10.00	10.00	10.00	.	10.00	12.00	13.00	13.00
R5009	Placebo	10.00	10.00	10.00	.	.	.	.	.	.	.
R5010	Active	20.00	20.00	10.00	10.00	10.00	5.00	.	.	.	.
R5011	Active	20.00	15.00	15.00	10.00	5.00	0.00	0.00	0.00	0.00	0.00
R5012	Placebo	70.00	2.00	2.50	2.00	.	.	.	.	.	.
R5013	Active	4.00	2.00	3.00	2.00	1.00	0.50	2.00	30.00	4.00	10.00

**CONFIDENTIAL**

**Listing 6: User Diary**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(USA)**

Subject ID	Group	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10
R5014	Placebo	8.00	6.00	6.00	5.00	4.00	4.00	3.00	3.00	2.00	2.00
R5015	Placebo	30.00	30.00	20.00	20.00	20.00	.	.	20.00	18.00	20.00
R5016	Placebo	7.00	7.00	6.00	8.00	10.00	10.00	.	.	.	.
R5017	Active	.	.	.	.	.	.	.	.	.	.
R5018	Active	8.00	7.00	7.00	6.00	8.00	.	7.00	5.00	5.00	6.00
R5019	Placebo	10.00	8.00	7.00	6.00	6.00	2.00	.	6.00	7.00	7.00
R5020	Active	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00	12.00	12.00
R5021	Placebo	12.00	10.00	8.00	7.00	4.00	.	0.00	0.00	0.00	4.00
R5022	Active	.	13.00	13.00	11.50	10.00	4.00	4.00	2.00	2.00	1.00
R5023	Active	7.00	7.00	5.00	4.00	5.00	5.00	5.00	5.00	2.00	.
R5024	Placebo	.	.	.	.	.	.	.	.	.	.
R5025	Placebo	15.00	15.00	15.00	15.00	15.00	15.00	10.00	10.00	10.00	17.00
R5026	Placebo	.	.	.	.	.	.	.	.	.	.
R5027	Active	10.00	7.00	5.00	4.00	0.00	0.00	0.00	0.00	0.00	0.00
R5028	Active	10.00	8.00	8.00	6.00	9.00	0.00	.	0.00	0.00	12.00
R3001	Active	5.00	5.00	5.00	2.00	2.00	0.00	0.00	0.00	0.00	0.00
R3002	Placebo	10.00	7.00	5.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R3003	Active	2.00	2.00	2.00	3.00	2.00	.	0.00	0.00	10.00	10.00
R3004	Placebo	20.00	20.00	18.00	12.00	13.00	.	10.00	10.00	8.00	8.00
R3005	Placebo	18.00	18.00	18.00	16.00	2.00	.	14.00	15.00	20.00	20.00
R3006	Active	10.00	6.00	4.00	4.00	2.00	.	1.00	1.00	1.00	1.00
R3007	Placebo	10.00	7.00	8.00	5.00	3.00	0.00	0.00	0.00	2.00	4.00
R3008	Placebo	10.00	10.00	5.00	1.00	1.00	1.00	0.00	0.00	0.00	0.00
R3009	Active	14.00	12.00	10.00	8.00	7.00	0.00	0.00	0.42	.	.
R3010	Placebo	10.00	6.00	4.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00
R3011	Active	18.00	14.00	10.00	8.00	10.00	0.00	0.00	0.00	0.00	.
R3012	Active	11.00	5.00	12.00	.	.	.	.	.	.	.
R3013	Active	7.00	6.00	5.00	3.00	1.00	.	0.00	0.00	0.00	0.00
R3014	Placebo	7.00	8.00	14.00	10.00	12.00	.	15.00	15.00	15.00	15.00
R3015	Placebo	.	.	.	.	.	.	.	.	.	.
R3016	Active	14.00	14.00	18.00	19.00	0.00	0.00	0.00	0.00	0.00	1.00
R3017	Active	5.00	5.00	6.00	0.00	0.00	.	.	.	.	.
R3018	Placebo	20.00	20.00	10.00	6.00	1.00	0.00	0.00	0.00	0.00	.
R3019	Placebo	10.00	6.00	8.00	8.00	7.00	.	6.00	6.00	7.00	7.00
R3020	Active	10.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	.
R3021	Active	.	.	.	.	.	.	.	.	.	.
R3022	Placebo	40.00	40.00	25.00	20.00	20.00	25.00	40.00	40.00	40.00	40.00
R3023	Placebo	10.00	8.00	8.00	8.00	2.00	.	.	.	.	.
R3024	Active	7.00	5.00	.	.	.	.	.	.	.	.
R3025	Placebo	6.00	5.00	5.00	3.00	2.00	5.00	5.00	10.00	10.00	.
R3026	Active	10.00	10.00	5.00	3.00	2.00	15.00	0.00	0.00	0.00	0.00
R3027	Active	20.00	20.00	18.00	20.00	20.00	.	20.00	20.00	20.00	.
R3028	Placebo	5.00	4.00	4.00	3.00	.	3.00	2.00	5.00	4.00	.
R3029	Placebo	13.00	14.00	12.00	11.00	9.00	.	.	.	.	.
R3030	Active	.	.	.	.	.	.	.	.	.	.
R3031	Active	7.00	7.00	5.00	3.00	1.00	.	.	0.00	2.00	.
R3032	Placebo	.	.	.	.	.	.	.	.	.	.
R2001	Active	.	.	.	.	.	.	.	.	.	.
R2002	Active	3.00	1.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00	.
R2003	Active	15.00	7.00	0.00	2.00	1.00	0.00	0.00	0.00	0.00	.

**CONFIDENTIAL**

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on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(USA)**

Subject ID	Group	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10
R2004	Placebo	15.00	11.00	6.00	6.00	4.00	.	.	.	.	.
R2005	Placebo	7.00	9.00	6.00	7.00	4.00	0.00	0.00	0.00	0.00	.
R2006	Placebo	16.00	10.00	5.00	4.00	1.00	.	4.00	5.00	8.00	0.00
R2007	Placebo	15.00	15.00	14.00	10.00	10.00	6.00	5.00	5.00	5.00	5.00
R2008	Active	12.00	8.00	8.00	8.00	8.00	.	.	.	.	.
R2009	Placebo	25.00	17.00	12.00	10.00	10.00	.	0.00	0.00	0.00	0.00
R2010	Active	10.00	7.00	5.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00
R2011	Placebo	15.00	14.00	10.00	8.00	10.00	.	5.00	5.00	8.00	5.00
R2012	Active	6.00	6.00	10.00	0.00	12.00	16.00	6.00	3.00	5.00	10.00
R2013	Active	20.00	0.00	10.00	20.00	.	10.00	0.00	8.00	0.00	1.00
R2014	Placebo	.	15.00	10.00	10.00	15.00	10.00	10.00	10.00	10.00	10.00
R2015	Active	8.00	8.00	8.00	7.00	.	5.00	2.00	2.00	10.00	10.00
R2016	Placebo	3.00	6.00	6.00	6.00	6.00	.	0.00	0.00	0.00	.
R2017	Active	10.00	8.00	5.00	3.00	3.00	0.00	0.00	0.00	3.00	5.00
R2018	Placebo	15.00	15.00	10.00	4.00	4.00	20.00	.	.	.	.
R2019	Placebo	15.00	10.00	10.00	7.00	15.00	10.00	10.00	10.00	10.00	8.00
R2020	Active	7.00	5.00	4.00	0.00	0.00	.	.	.	.	.
R2021	Active	10.00	10.00	10.00	10.00	10.00	10.00	0.00	0.00	0.00	0.00
R2022	Placebo	4.00	3.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	5.00
R2023	Placebo	6.00	4.00	3.00	2.00	1.00	1.00	0.00	0.00	0.00	0.00
R2024	Active	7.00	7.00	5.00	5.00	5.00	0.00	0.00	0.00	0.00	0.00
R2025	Active	3.00	3.00	2.00	3.00	4.00	1.00	2.00	2.00	2.00	.
R2026	Active	12.00	10.00	10.00	12.00	12.00	10.00	10.00	8.00	8.00	8.00
R2027	Active	20.00	20.00	15.00	8.00	5.00	5.00	3.00	5.00	15.00	5.00
R2028	Placebo	9.00	9.00	8.00	8.00	8.00	10.00	8.00	12.00	15.00	10.00
R2029	Placebo	49.00	33.00	25.00	15.00	9.00	14.00	18.00	24.00	20.00	15.00
R2030	Placebo	12.00	10.00	10.00	8.00	8.00	6.00	.	.	.	.
R2031	Placebo	7.00	6.00	5.00	5.00	4.00	1.00	0.00	0.00	0.00	0.00
R2032	Active	5.00	7.00	5.00	3.00	1.00	0.00	0.00	0.00	0.00	.
R4001	Placebo	14.00	10.00	2.00	1.00	1.00	0.00	0.00	1.00	0.00	0.00
R4002	Active	10.00	10.00	10.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R4003	Placebo	0.00	7.00	10.00	7.00	10.00	8.00	15.00	20.00	12.00	15.00
R4004	Active	12.00	10.00	5.00	3.00	.	.	.	.	.	.
R4005	Active	10.00	10.00	8.00	8.00	6.00	0.70	0.70	0.70	0.70	0.70
R4006	Placebo	8.00	8.00	10.00	10.00	.	.	.	.	.	.
R4007	Active	8.00	5.00	5.00	10.00	10.00	12.00	12.00	15.00	20.00	15.00
R4008	Active	9.00	12.00	12.00	9.00	7.00	8.00	5.00	5.00	12.00	15.00
R4009	Placebo	.	10.00	.	.	5.00	4.00	4.00	5.00	7.00	.
R4010	Placebo	14.00	10.00	5.00	5.00	5.00	5.00	5.00	3.00	1.00	2.00
R4011	Placebo	6.00	9.00	9.00	9.00	5.00	7.00	6.00	6.00	10.00	15.00
R4012	Active	1.00	1.00	3.00	3.00	0.00	0.00	0.00	0.00	1.00	0.00
R4013	Active	17.00	15.00	13.00	10.00	7.00	.	.	.	.	.
R4014	Placebo	5.00	5.00	5.00	2.00	2.00	5.00	5.00	5.00	5.00	5.00
R4015	Placebo	15.00	12.00	12.00	10.00	4.00	2.00	6.00	12.00	14.00	15.00
R4016	Active	8.00	4.00	3.00	2.00	2.00	1.00	0.00	1.00	0.00	1.00
R4017	Active	13.00	9.00	1.50	2.00	4.30	11.00	10.00	11.00	14.00	11.00
R4018	Placebo	10.00	15.00	15.00	15.00	15.00	15.00	15.00	12.00	15.00	20.00
R4019	Placebo	6.00	6.00	5.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R4020	Active	15.00	15.00	10.00	10.00	0.00	0.00	0.00	0.00	0.00	0.00
R4021	Placebo	30.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	15.00

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on the Quit Rate among Cigarette Smokers who wish to stop smoking.

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**Average number of Cigarettes per day  
(USA)**

Subject ID	Group	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10
R4022	Active	3.00	3.00	3.00	3.00	2.00	1.00	1.00	2.00	2.00	2.00
R4023	Placebo	7.00	4.00	4.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00
R4024	Active	13.00	7.00	3.00	4.00	10.00	.	.	.	.	.
R4025	Active	30.00	20.00	30.00	20.00	20.00	.	.	.	.	.
R4026	Placebo	8.00	7.00	8.00	6.00	6.00	.	2.00	1.00	1.00	1.50
R4027	Active	10.00	10.00	5.00	3.00	0.00	0.00	0.00	0.00	0.00	0.00
R4028	Active	30.00	20.00	20.00	20.00	20.00	20.00	15.00	15.00	15.00	25.00
R4029	Placebo	10.00	10.00	7.00	4.00	1.00	0.00	2.00	0.00	0.00	0.25
R4030	Placebo	15.00	20.00	20.00	15.00	10.00	15.00	15.00	10.00	10.00	.
R4031	Placebo	7.00	8.00	6.00	.	.	.	.	.	.	.
R4032	Placebo	6.00	6.00	5.00	5.00	5.00	8.00	6.00	6.00	6.00	4.00
R4033	Active	5.00	5.00	2.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R4034	Active	8.00	10.00	7.00	.	.	.	.	.	.	.
R4035	Active	13.00	13.00	18.00	18.00	18.00	20.00	15.00	20.00	20.00	18.00
R4036	Placebo	5.00	5.00	7.00	7.00	7.00	0.00	0.00	1.00	1.00	2.00
R4037	Placebo	5.00	2.00	2.00	2.00	2.00	4.00	6.00	5.00	7.00	4.00
R4038	Placebo	25.00	25.00	30.00	8.00	10.00	.	.	12.00	12.00	12.00
R4039	Active	15.00	15.00	17.00	18.00	15.00	18.00	18.00	17.00	18.00	17.00
R4040	Active	19.00	20.00	20.00	15.00	10.00	0.00	0.00	0.00	0.00	0.00
R4041	Placebo	13.00	14.00	16.00	12.00	12.00	12.00	13.00	13.00	15.00	20.00
R4042	Active	10.00	7.00	7.00	5.00	7.00	7.00	8.00	7.00	10.00	10.00
R4043	Active	1.00	5.00	5.00	15.00	20.00	.	.	.	.	.
R4044	Active	6.00	5.00	1.00	1.00	6.00	2.00	2.00	6.00	.	.
R4045	Placebo	12.00	12.00	10.00	12.00	3.00	2.00	0.00	0.71	2.29	3.00
R4046	Placebo	9.00	14.00	9.00	12.00	8.00	10.00	14.00	18.00	20.00	.
R4047	Placebo	8.00	13.00	15.00	15.00	15.00	18.00	15.00	18.00	18.00	18.00
R4048	Active	5.00	10.00	12.00	12.00	15.00	14.00	12.00	13.00	12.00	12.00
R4049	Active	15.00	12.00	18.00	18.00	14.00	3.00	6.00	7.00	10.00	15.00
R4050	Placebo	27.00	27.00	28.00	25.00	24.00	20.00	19.00	20.00	20.00	15.00
R4051	Active	5.00	3.00	3.00	2.00	1.00	2.00	2.00	3.00	3.00	2.00
R4052	Placebo	2.60	4.00	6.00	7.10	7.90	8.00	9.00	8.00	10.00	6.00
R4053	Active	30.00	15.00	10.00	10.00	20.00	20.00	20.00	20.00	.	.
R4054	Placebo	20.00	20.00	15.00	4.00	10.00	20.00	20.00	20.00	20.00	20.00
R4055	Active	3.00	2.00	2.00	1.00	2.00	1.00	3.00	1.00	2.00	0.29
R4056	Active	15.00	12.00	10.00	10.00	10.00	8.00	8.00	8.00	8.00	8.00
R4057	Active	17.00	14.00	15.00	12.00	10.00	15.00	15.00	15.00	14.00	15.00
R4058	Placebo	11.00	10.00	10.00	10.00	9.00	10.00	10.00	10.00	11.00	10.00
R4059	Placebo	10.00	7.00	5.00	7.00	7.00	.	.	8.00	7.00	7.00
R4060	Placebo	10.00	10.00	9.00	15.00	15.00	15.00	15.00	20.00	16.00	18.00
R4061	Active	20.00	20.00	15.00	20.00	20.00	.	.	.	.	.
R4062	Placebo	15.00	14.00	14.00	14.00	12.00	12.00	12.00	10.00	10.00	10.00
R4063	Active	9.00	6.00	6.00	6.00	4.00	5.00	2.00	3.00	2.00	3.00
R4064	Placebo	10.00	10.00	10.00	10.00	10.00	8.00	8.00	8.00	8.00	8.00
R4065	Active	15.00	13.00	9.00	5.00	13.00	11.00	10.00	10.00	12.00	10.00
R4066	Placebo	6.00	4.00	8.00	7.00	6.00	.	.	.	.	.
R4067	Placebo	14.00	12.00	12.00	18.00	15.00	.	.	.	.	.
R4068	Active	15.00	15.00	10.00	3.00	3.00	15.00	10.00	15.00	15.00	10.00
R4069	Active	18.00	16.00	14.00	12.00	10.00	10.00	10.00	10.00	10.00	10.00
R4070	Placebo	5.00	15.00	10.00	10.00	20.00	13.00	13.00	10.00	10.00	15.00
R4071	Active	3.00	3.00	2.00	1.00	0.00	0.00	0.00	0.00	0.00	0.00

**CONFIDENTIAL**

**Listing 6: User Diary**

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on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(USA)**

<b>Subject ID</b>	<b>Group</b>	<b>Week 1</b>	<b>Week 2</b>	<b>Week 3</b>	<b>Week 4</b>	<b>Week 5</b>	<b>Week 6</b>	<b>Week 7</b>	<b>Week 8</b>	<b>Week 9</b>	<b>Week 10</b>
R4072	Placebo	34.00	26.00	18.00	18.00	18.00	18.00	18.00	18.00	17.00	17.00
R4073	Active	.	.	.	.	.	.	.	.	.	.
R4074	Placebo	8.00	8.00	6.00	3.00	2.00	.	.	.	.	.
R4075	Active	10.00	10.00	10.00	2.00	2.00	5.00	7.00	7.00	12.00	5.00
R4076	Placebo	20.00	20.00	19.00	20.00	20.00	1.50	1.50	18.00	16.00	.
R4077	Active	7.00	10.00	6.00	7.00	3.00	8.00	7.00	7.00	7.00	9.00
R4078	Placebo	18.00	35.00	30.00	35.00	35.00	35.00	35.00	35.00	35.00	.
R4079	Placebo	9.00	6.00	6.00	5.00	5.00	6.00	6.00	5.00	7.00	7.00
R4080	Active	.	.	.	.	.	.	.	.	.	.
R4081	Active	10.00	12.00	10.00	10.00	10.00	.	.	.	.	.
R4082	Placebo	20.00	20.00	20.00	20.00	20.00	.	.	.	.	.
R4083	Active	10.00	8.00	8.00	0.00	0.00	0.00	0.00	0.00	0.00	2.00
R4084	Placebo	15.00	18.00	15.00	15.00	12.00	14.00	10.00	5.00	10.00	.
R4085	Active	.	.	.	.	.	.	.	.	.	.
R4086	Active	11.00	11.00	8.00	6.00	.	3.00	.	.	.	.
R4087	Placebo	7.00	7.00	10.00	12.00	15.00	10.00	10.00	10.00	15.00	10.00
R4088	Placebo	15.00	12.00	5.00	5.00	15.00	.	.	.	.	.
R4089	Placebo	6.00	7.00	5.00	6.00	7.00	6.00	7.00	6.00	7.00	6.00
R4090	Active	12.00	8.00	6.00	5.00	3.00	0.00	0.00	0.00	0.00	0.00
R4091	Active	16.00	10.00	10.00	2.00	1.86	1.00	2.00	2.00	3.00	2.00
R4092	Active	40.00	31.00	30.00	30.00	50.00	30.00	30.00	30.00	30.00	40.00
R4093	Placebo	15.00	14.00	13.00	12.00	10.00	10.00	10.00	9.00	9.00	9.00
R4094	Placebo	5.00	5.00	3.00	2.00	5.00	2.00	2.00	2.00	2.00	6.00
R4095	Active	.	.	.	.	.	.	.	.	.	.
R4096	Placebo	9.00	8.00	7.00	5.00	2.00	4.00	5.00	7.00	9.00	8.00
R4097	Active	12.00	12.00	12.00	10.00	8.00	10.00	12.00	10.00	12.00	12.00
R4098	Placebo	20.00	20.00	16.00	15.00	20.00	.	.	.	.	.
R4099	Active	3.00	2.00	2.00	1.00	1.00	1.00	1.00	1.00	0.00	0.00
R4100	Active	4.00	3.00	3.00	3.00	0.00	0.00	0.00	0.00	0.00	0.00
R4101	Placebo	.	.	.	.	.	.	.	.	.	.
R4102	Placebo	8.00	5.00	2.00	2.00	0.14	3.00	0.00	0.00	0.00	0.00
R4103	Placebo	10.00	9.00	9.00	7.00	7.00	.	.	.	.	.
R4104	Placebo	.	.	.	.	.	.	.	.	.	.
R4105	Active	3.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R4106	Active	6.00	6.00	10.00	4.00	11.00	6.00	6.00	6.00	6.00	.
R4107	Active	9.00	5.00	5.00	8.00	1.00	2.00	2.00	2.00	2.00	4.00
R4108	Placebo	7.00	7.00	12.00	15.00	12.00	.	.	.	.	.
R4109	Placebo	8.00	12.00	8.00	10.00	16.00	.	.	.	.	.
R4110	Active	9.00	5.00	6.00	7.00	9.00	.	.	.	.	.
R4111	Placebo	.	.	.	.	.	.	.	.	.	.
R4112	Active	10.00	6.00	15.00	15.00	10.00	.	.	.	.	.
R4113	Active	6.00	6.00	5.00	5.00	5.00	5.00	5.00	5.00	4.00	3.00
R4114	Placebo	6.00	4.00	3.00	.	4.00	3.00	0.00	0.00	0.00	4.00
R4115	Active	10.00	9.00	10.00	9.00	10.00	.	.	.	.	.
R4116	Placebo	0.00	4.00	2.00	0.00	5.00	3.00	2.00	2.00	2.00	0.00
R4117	Active	10.00	3.00	3.00	0.43	4.00	3.00	6.00	4.00	6.00	3.00
R4118	Placebo	10.00	6.00	5.00	5.00	5.00	5.00	10.00	5.00	5.00	5.00
R4119	Placebo	13.00	10.00	8.00	7.00	20.00	10.00	10.00	10.00	12.00	10.00
R4120	Active	10.00	10.00	6.00	3.00	3.00	5.00	5.00	8.00	10.00	4.00
R4121	Placebo	.	.	.	.	.	.	.	.	.	.

**CONFIDENTIAL**

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A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(USA)**

<b>Subject ID</b>	<b>Group</b>	<b>Week 11</b>	<b>Week 12</b>	<b>Week 13</b>	<b>Week 14</b>	<b>Week 15</b>	<b>Week 16</b>	<b>Week 17</b>	<b>Week 18</b>	<b>Week 19</b>	<b>Week 20</b>
R1001	Active	0.00	0.00	0.00	3.00	5.00	5.00	4.00	4.00	3.00	3.00
R1002	Placebo	4.00	6.00	5.00	5.00	4.00	10.00	10.00	10.00	5.00	10.00
R1003	Active	.	.	.	.	.	.	.	.	.	.
R1004	Placebo	2.00	1.00	1.00	1.00	1.00	5.00	2.00	3.00	2.00	2.00
R1005	Active	1.00	2.00	0.00	0.00	2.00	3.00	0.00	0.00	0.00	0.00
R1006	Placebo	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
R1007	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R1008	Placebo	.	.	.	.	.	.	.	.	.	.
R1009	Active	.	.	.	.	.	.	.	.	.	.
R1010	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R1011	Placebo	10.00	10.00	15.00	15.00	15.00	15.00	20.00	15.00	20.00	20.00
R1012	Placebo	10.00	15.00	10.00	10.00	12.00	15.00	10.00	10.00	10.00	11.00
R1013	Placebo	6.00	3.00	3.00	1.00	1.00	1.00	3.00	4.00	4.00	6.00
R1014	Placebo	.	.	.	.	.	.	.	.	.	.
R1015	Active	0.40	0.40	0.40	0.40	0.40	0.40	0.40	0.30	0.30	0.30
R1016	Active	7.00	3.00	4.00	5.00	7.00	6.00	4.00	7.00	17.00	3.00
R1017	Active	5.00	5.00	4.00	4.00	4.00	4.00	5.00	5.00	5.00	5.00
R1018	Placebo	.	.	.	.	.	.	.	.	.	.
R1019	Active	5.00	5.00	5.00	5.00	5.00	4.00	5.00	5.00	5.00	7.00
R1020	Placebo	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.00
R1021	Placebo	2.00	2.00	2.00	3.00	8.00	5.00	5.00	8.00	5.00	5.00
R1022	Active	5.00	5.00	8.00	6.00	10.00	6.00	5.00	5.00	7.00	10.00
R1023	Placebo	.	.	.	.	.	.	.	.	.	.
R1024	Active	10.00	10.00	15.00	15.00	15.00	15.00	12.00	12.00	15.00	15.00
R1025	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R1026	Active	5.00	4.00	6.00	0.00	4.00	8.00	5.00	5.00	5.00	6.00
R1027	Placebo	.	.	.	.	.	.	.	.	.	.
R1028	Placebo	6.00	4.00	4.00	4.00	6.00	4.00	6.00	6.00	8.00	4.00
R1029	Active	.	.	.	.	.	.	.	.	.	.
R1030	Placebo	5.00	3.00	2.00	3.00	2.00	2.00	5.00	5.00	10.00	10.00
R1031	Active	15.00	10.00	5.00	15.00	.	8.00	5.00	7.00	10.00	10.00
R1032	Active	0.00	0.00	0.00	0.00	0.00	0.00	.	.	.	.
R1033	Placebo	.	.	.	.	.	.	.	.	.	.
R1034	Placebo	7.00	6.00	5.00	6.00	4.00	3.00	4.00	6.00	6.00	4.00
R1035	Active	12.00	13.00	13.00	13.00	13.00	13.00	14.00	15.00	16.00	16.00
R1036	Placebo	.	.	.	.	.	.	.	.	.	.
R1037	Active	5.00	5.00	5.00	0.00	0.00	0.00	5.00	20.00	20.00	20.00
R5001	Placebo	10.00	10.00	10.00	10.00	10.00	15.00	15.00	15.00	15.00	15.00
R5002	Active	0.00	0.00	0.00	0.00	10.00	10.00	20.00	20.00	20.00	20.00
R5003	Placebo	15.00	15.00	15.00	10.00	10.00	15.00	12.00	12.00	12.00	12.00
R5004	Active	9.00	8.00	8.00	6.00	6.00	6.00	8.00	8.00	10.00	13.00
R5005	Placebo	.	.	.	.	.	.	.	.	.	.
R5006	Active	10.00	15.00	15.00	5.00	5.00	20.00	20.00	20.00	20.00	20.00
R5007	Active	.	.	.	.	.	.	.	.	.	.
R5008	Placebo	8.00	10.00	10.00	10.00	10.00	10.00	6.00	6.00	8.00	6.00
R5009	Placebo	.	.	.	.	.	.	.	.	.	.
R5010	Active	.	.	.	.	.	.	.	.	.	.
R5011	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R5012	Placebo	.	.	.	.	.	.	.	.	.	.
R5013	Active	1.00	1.00	1.00	1.00	1.00	1.00	2.00	2.00	2.00	4.00

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**Average number of Cigarettes per day  
(USA)**

Subject ID	Group	Week 11	Week 12	Week 13	Week 14	Week 15	Week 16	Week 17	Week 18	Week 19	Week 20
R5014	Placebo	3.00	4.00	4.00	2.00	2.00	1.00	1.00	.	.	.
R5015	Placebo	20.00	20.00	20.00	20.00	15.00	15.00	20.00	20.00	20.00	15.00
R5016	Placebo	.	.	.	.	.	.	.	.	.	.
R5017	Active	.	.	.	.	.	.	.	.	.	.
R5018	Active	5.00	3.00	4.00	4.00	4.00	5.00	6.00	6.00	5.00	6.00
R5019	Placebo	6.00	8.00	10.00	12.00	10.00	12.00	10.00	10.00	11.00	10.00
R5020	Active	12.00	12.00	10.00	7.00	5.00	5.00	2.00	2.00	2.00	2.00
R5021	Placebo	1.00	0.00	2.00	0.00	0.00	2.00	.	.	.	.
R5022	Active	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	2.00	2.00
R5023	Active	1.00	2.00	2.00	1.00	1.00	2.00	1.00	1.00	1.00	2.00
R5024	Placebo	.	.	.	.	.	.	.	.	.	.
R5025	Placebo	10.00	10.00	10.00	10.00	10.00	10.00	13.00	13.00	.	.
R5026	Placebo	.	.	.	.	.	.	.	.	.	.
R5027	Active	0.00	0.00	0.00	0.00	0.00	0.00	.	.	.	.
R5028	Active	12.00	8.00	6.00	4.00	4.00	3.00	8.00	6.00	6.00	5.00
R3001	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R3002	Placebo	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R3003	Active	0.00	0.00	0.00	0.00	0.00	0.00	.	.	.	.
R3004	Placebo	9.00	9.00	9.00	9.00	6.00	4.00	4.00	4.00	4.00	5.00
R3005	Placebo	25.00	20.00	20.00	22.00	.	.	.	.	.	.
R3006	Active	1.00	1.00	1.00	1.00	1.00	0.00	1.00	1.00	1.00	1.00
R3007	Placebo	6.00	10.00	8.00	8.00	8.00	8.00	10.00	10.00	10.00	10.00
R3008	Placebo	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R3009	Active	.	.	.	.	.	.	.	.	.	.
R3010	Placebo	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R3011	Active	.	.	.	.	.	0.00	0.00	0.00	0.00	0.00
R3012	Active	.	.	.	.	.	.	.	.	.	.
R3013	Active	0.00	0.00	1.00	0.00	0.00	1.00	0.00	0.00	0.00	0.00
R3014	Placebo	.	.	.	.	.	.	.	.	.	.
R3015	Placebo	.	.	.	.	.	.	.	.	.	.
R3016	Active	0.00	0.00	0.00	1.00	0.00	1.00	1.00	1.00	2.00	2.00
R3017	Active	.	.	.	.	.	.	.	.	.	.
R3018	Placebo	0.00	1.00	0.00	1.00	0.00	0.00	0.00	.	.	.
R3019	Placebo	8.00	9.00	10.00	9.00	11.00	15.00	15.00	16.00	15.00	15.00
R3020	Active	.	.	.	.	.	0.00	0.00	0.00	0.00	0.00
R3021	Active	.	.	.	.	.	.	.	.	.	.
R3022	Placebo	40.00	40.00	40.00	40.00	40.00	40.00	40.00	40.00	40.00	30.00
R3023	Placebo	.	.	.	.	.	.	.	.	.	.
R3024	Active	.	.	.	.	.	.	.	.	.	.
R3025	Placebo	.	.	.	.	.	.	.	.	.	.
R3026	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R3027	Active	.	.	.	.	.	.	.	.	.	.
R3028	Placebo	.	.	.	.	.	.	5.00	7.00	7.00	10.00
R3029	Placebo	.	.	.	.	.	.	.	.	.	.
R3030	Active	.	.	.	.	.	.	.	.	.	.
R3031	Active	.	.	.	.	.	.	.	.	.	3.00
R3032	Placebo	.	.	.	.	.	.	.	.	.	.
R2001	Active	.	.	.	.	.	.	.	.	.	.
R2002	Active	0.00	0.00	0.00	0.00	0.00	2.00	0.00	0.00	0.00	0.00
R2003	Active	0.00	0.00	0.00	0.00	1.00	0.00	0.00	0.00	0.00	0.00

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**Average number of Cigarettes per day  
(USA)**

Subject ID	Group	Week 11	Week 12	Week 13	Week 14	Week 15	Week 16	Week 17	Week 18	Week 19	Week 20
R2004	Placebo	.	.	.	.	.	.	.	.	.	.
R2005	Placebo	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R2006	Placebo	0.00	3.00	5.00	0.00	0.00	1.00	5.00	.	.	.
R2007	Placebo	5.00	5.00	3.00	5.00	5.00	5.00	6.00	6.00	6.00	6.00
R2008	Active	.	.	.	.	.	.	.	.	.	.
R2009	Placebo	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R2010	Active	3.00	3.00	2.00	2.00	2.00	2.00	3.00	3.00	3.00	3.00
R2011	Placebo	10.00	4.00	10.00	9.00	10.00	12.00	5.00	4.00	10.00	8.00
R2012	Active	6.00	10.00	4.00	15.00	5.00	3.00	6.00	0.00	2.00	2.00
R2013	Active	.	.	.	.	.	5.00	0.00	0.00	1.00	.
R2014	Placebo	5.00	5.00	5.00	5.00	5.00	5.00	15.00	15.00	15.00	15.00
R2015	Active	8.00	20.00	15.00	15.00	15.00	15.00	8.00	12.00	9.00	11.00
R2016	Placebo	0.00	0.00	4.00	4.00	0.00	7.00	10.00	.	10.00	10.00
R2017	Active	5.00	5.00	5.00	3.00	10.00	10.00	10.00	6.00	15.00	10.00
R2018	Placebo	.	.	.	.	.	.	.	.	.	.
R2019	Placebo	8.00	10.00	10.00	8.00	10.00	10.00	14.00	15.00	10.00	15.00
R2020	Active	.	.	.	.	.	.	.	.	.	.
R2021	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	2.00
R2022	Placebo	6.00	5.00	10.00	8.00	7.00	5.00	.	.	.	5.00
R2023	Placebo	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R2024	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R2025	Active	.	.	.	.	.	.	.	.	.	.
R2026	Active	12.00	10.00	10.00	12.00	12.00	10.00	15.00	15.00	15.00	20.00
R2027	Active	3.00	10.00	14.00	10.00	15.00	20.00	20.00	20.00	25.00	20.00
R2028	Placebo	10.00	10.00	0.00	10.00	10.00	10.00	10.00	10.00	10.00	15.00
R2029	Placebo	12.00	9.00	8.00	9.00	7.00	7.00	15.00	22.00	18.00	7.00
R2030	Placebo	.	.	.	.	.	.	.	.	.	.
R2031	Placebo	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R2032	Active	.	.	.	.	.	.	.	.	.	.
R4001	Placebo	0.00	0.00	0.00	0.00	0.00	2.00	.	.	.	.
R4002	Active	0.00	0.00	0.00	0.00	0.00	.	0.00	0.00	0.00	0.00
R4003	Placebo	18.00	20.00	15.00	20.00	20.00	12.00	20.00	20.00	20.00	20.00
R4004	Active	.	.	.	.	.	.	.	.	.	.
R4005	Active	0.00	0.00	0.70	0.40	.	3.60	3.00	3.00	3.00	3.00
R4006	Placebo	.	.	.	.	.	.	.	.	.	.
R4007	Active	20.00	20.00	20.00	20.00	20.00	18.00	20.00	15.00	15.00	20.00
R4008	Active	10.00	5.00	20.00	12.00	8.00	5.00	10.00	15.00	12.00	12.00
R4009	Placebo	6.00	6.00	6.00	.	5.00	5.00	.	.	.	.
R4010	Placebo	2.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	7.00
R4011	Placebo	15.00	15.00	15.00	10.00	10.00	20.00	15.00	20.00	20.00	20.00
R4012	Active	0.00	0.00	0.00	0.00	0.00	0.00	1.00	0.00	1.00	.
R4013	Active	.	.	.	.	.	.	.	.	.	.
R4014	Placebo	5.00	5.00	3.00	3.00	3.00	5.00	.	.	.	.
R4015	Placebo	16.00	20.00	18.00	16.00	15.00	16.00	16.00	16.00	16.00	16.00
R4016	Active	0.00	0.00	0.00	0.00	0.00	2.00	11.00	10.00	11.00	10.00
R4017	Active	11.00	13.00	11.00	11.00	11.00	11.00	11.00	11.00	11.00	9.00
R4018	Placebo	15.00	15.00	15.00	15.00	15.00	15.00	20.00	20.00	20.00	20.00
R4019	Placebo	0.00	0.00	0.00	5.00	7.00	6.00	10.00	10.00	6.00	6.00
R4020	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R4021	Placebo	15.00	15.00	15.00	15.00	15.00	20.00	.	.	.	.

**CONFIDENTIAL**

**Listing 6: User Diary**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(USA)**

Subject ID	Group	Week 11	Week 12	Week 13	Week 14	Week 15	Week 16	Week 17	Week 18	Week 19	Week 20
R4022	Active	3.00	2.00	2.00	0.00	2.00	1.00	.	.	.	.
R4023	Placebo	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R4024	Active	.	.	.	.	.	.	.	.	.	.
R4025	Active	.	.	.	.	.	.	.	.	.	.
R4026	Placebo	3.00	3.00	3.00	3.00	3.00	3.00	6.00	6.00	6.00	5.00
R4027	Active	0.00	0.00	0.00	0.00	0.00	0.00	2.00	2.00	2.00	2.00
R4028	Active	25.00	40.00	40.00	40.00	40.00	.	25.00	25.00	25.00	25.00
R4029	Placebo	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R4030	Placebo	.	.	.	.	.	.	.	.	.	.
R4031	Placebo	.	.	.	.	.	.	.	.	.	.
R4032	Placebo	4.00	4.00	2.00	0.00	0.00	0.00	0.00	10.00	10.00	6.00
R4033	Active	0.00	0.00	0.00	0.00	0.00	.	0.00	0.00	0.00	0.00
R4034	Active	.	.	.	.	.	.	.	.	.	.
R4035	Active	18.00	18.00	14.00	15.00	.	.	17.00	15.00	18.00	18.00
R4036	Placebo	1.00	1.00	2.00	1.00	1.00	1.00	2.00	2.00	2.00	2.00
R4037	Placebo	5.00	5.00	4.00	4.00	4.00	4.00	4.00	3.00	3.00	3.00
R4038	Placebo	12.00	12.00	10.00	10.00	8.00	8.00	8.00	8.00	8.00	8.00
R4039	Active	20.00	21.00	20.00	20.00	20.00	20.00	22.00	20.00	19.00	20.00
R4040	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R4041	Placebo	15.00	20.00	20.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00
R4042	Active	10.00	10.00	10.00	12.00	10.00	10.00	.	.	.	.
R4043	Active	.	.	.	.	.	.	.	.	.	.
R4044	Active	.	.	.	.	.	.	.	.	.	.
R4045	Placebo	4.00	4.00	4.00	6.00	5.00	6.00	9.00	10.00	12.00	10.00
R4046	Placebo	.	.	.	.	.	.	.	.	.	.
R4047	Placebo	18.00	18.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00
R4048	Active	17.00	.	.	.	.	.	.	.	.	.
R4049	Active	15.00	15.00	15.00	15.00	20.00	20.00	20.00	15.00	15.00	15.00
R4050	Placebo	14.00	10.00	9.00	9.00	8.00	8.00	11.00	10.00	10.00	10.00
R4051	Active	2.00	2.00	1.00	1.00	2.00	2.00	2.00	2.00	2.00	2.00
R4052	Placebo	6.00	6.00	6.00	4.00	4.00	2.00	6.00	5.00	4.00	8.00
R4053	Active	.	.	.	.	.	.	.	.	.	.
R4054	Placebo	15.00	15.00	12.00	12.00	18.00	20.00	20.00	20.00	25.00	25.00
R4055	Active	0.29	4.00	4.00	2.00	4.00	10.00	10.00	10.00	10.00	10.00
R4056	Active	8.00	7.00	7.00	8.00	12.00	.	.	.	.	.
R4057	Active	15.00	15.00	15.00	15.00	15.00	15.00	15.00	20.00	20.00	20.00
R4058	Placebo	10.00	12.00	12.00	11.00	12.00	15.00	15.00	15.00	18.00	17.00
R4059	Placebo	7.00	6.00	6.00	6.00	6.00	2.00	2.00	0.00	0.00	0.00
R4060	Placebo	19.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00	19.00	19.00
R4061	Active	.	.	.	.	.	.	.	.	.	.
R4062	Placebo	8.00	8.00	8.00	8.00	10.00	10.00	10.00	10.00	10.00	10.00
R4063	Active	3.00	4.00	2.00	0.00	2.00	0.00	3.00	4.00	5.00	3.00
R4064	Placebo	8.00	6.00	10.00	10.00	10.00	8.00	.	.	.	.
R4065	Active	11.00	12.00	10.00	12.00	10.00	7.00	10.00	10.00	5.00	5.00
R4066	Placebo	.	.	.	.	.	.	.	.	.	.
R4067	Placebo	.	.	.	.	.	.	.	.	.	.
R4068	Active	15.00	20.00	10.00	0.00	20.00	20.00	20.00	20.00	20.00	20.00
R4069	Active	10.00	10.00	10.00	8.00	8.00	7.00	10.00	10.00	10.00	10.00
R4070	Placebo	15.00	15.00	15.00	15.00	15.00	15.00	20.00	20.00	20.00	20.00
R4071	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

**CONFIDENTIAL**

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A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(USA)**

<b>Subject ID</b>	<b>Group</b>	<b>Week 11</b>	<b>Week 12</b>	<b>Week 13</b>	<b>Week 14</b>	<b>Week 15</b>	<b>Week 16</b>	<b>Week 17</b>	<b>Week 18</b>	<b>Week 19</b>	<b>Week 20</b>
R4072	Placebo	16.00	15.00	16.00	17.00	16.00	16.00	15.00	16.00	15.00	15.00
R4073	Active	.	.	.	.	.	.	.	.	.	.
R4074	Placebo	.	.	.	.	.	.	.	.	.	.
R4075	Active	0.00	0.00	0.00	0.00	20.00	20.00	.	.	.	.
R4076	Placebo	.	.	.	.	.	.	.	.	.	.
R4077	Active	6.00	6.00	5.00	5.00	5.00	4.00	.	.	.	.
R4078	Placebo	.	.	.	.	.	.	.	.	.	.
R4079	Placebo	7.00	5.00	4.00	5.00	5.00	7.00	8.00	8.00	7.00	7.00
R4080	Active	.	.	.	.	.	.	.	.	.	.
R4081	Active	.	.	.	.	.	.	.	.	.	.
R4082	Placebo	.	.	.	.	.	.	.	.	.	.
R4083	Active	5.00	6.00	3.00	3.00	3.00	4.00	2.00	2.00	3.00	3.00
R4084	Placebo	.	.	.	.	.	.	.	.	.	.
R4085	Active	.	.	.	.	.	.	.	.	.	.
R4086	Active	.	.	.	.	.	.	.	.	.	.
R4087	Placebo	10.00	10.00	10.00	.	.	.	.	.	.	.
R4088	Placebo	.	.	.	.	.	.	.	.	.	.
R4089	Placebo	6.00	6.00	7.00	7.00	7.00	8.00	.	.	.	.
R4090	Active	0.00	0.00	0.00	0.00	0.00	0.00	1.00	0.00	0.00	0.00
R4091	Active	2.00	5.00	2.00	1.00	1.00	0.00	.	.	.	.
R4092	Active	40.00	40.00	40.00	40.00	40.00	40.00	40.00	40.00	40.00	40.00
R4093	Placebo	9.00	9.00	8.00	8.00	8.00	8.00	8.00	8.00	8.00	8.00
R4094	Placebo	6.00	4.00	4.00	4.00	6.00	4.00	6.00	4.00	4.00	6.00
R4095	Active	.	.	.	.	.	.	.	.	.	.
R4096	Placebo	10.00	10.00	10.00	11.00	10.00	10.00	8.00	9.00	9.00	7.00
R4097	Active	12.00	12.00	10.00	10.00	10.00	10.00	12.00	10.00	12.00	10.00
R4098	Placebo	.	.	.	.	.	.	.	.	.	.
R4099	Active	0.00	0.00	0.00	.	0.00	0.00	0.00	0.00	1.00	0.00
R4100	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R4101	Placebo	.	.	.	.	.	.	.	.	.	.
R4102	Placebo	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R4103	Placebo	.	.	.	.	.	.	.	.	.	.
R4104	Placebo	.	.	.	.	.	.	.	.	.	.
R4105	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R4106	Active	.	.	.	.	.	.	.	.	.	.
R4107	Active	4.00	4.00	10.00	3.00	3.00	2.00	4.00	6.00	6.00	6.00
R4108	Placebo	.	.	.	.	.	.	.	.	.	.
R4109	Placebo	.	.	.	.	.	.	.	.	.	.
R4110	Active	.	.	.	.	.	.	.	.	.	.
R4111	Placebo	.	.	.	.	.	.	.	.	.	.
R4112	Active	.	.	.	.	.	.	.	.	.	.
R4113	Active	3.00	3.00	3.00	3.00	3.00	3.00	4.00	4.00	5.00	5.00
R4114	Placebo	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00	4.00
R4115	Active	.	.	.	.	.	.	.	.	.	.
R4116	Placebo	2.00	2.00	3.00	2.00	0.00	3.00	3.00	3.00	2.00	2.00
R4117	Active	0.00	0.00	4.00	2.00	6.00	1.00	4.00	3.00	4.00	4.00
R4118	Placebo	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00
R4119	Placebo	8.00	8.00	8.00	7.00	8.00	7.00	9.00	9.00	8.00	8.00
R4120	Active	4.00	6.00	6.00	7.00	8.00	10.00	.	.	.	.
R4121	Placebo	.	.	.	.	.	.	.	.	.	.

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Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(USA)**

Subject ID	Group	Week 21	Week 22	Week 23	Week 24	Week 25	Week 26	Week 27	Week 28
R1001	Active	3.00	3.00	0.00	0.00	4.00	4.00	5.00	4.00
R1002	Placebo	3.00	10.00	4.00	10.00	7.00	7.00	10.00	3.00
R1003	Active	.	.	.	.	.	.	.	.
R1004	Placebo	1.00	2.00	0.00	2.00	0.00	0.00	2.00	3.00
R1005	Active	0.00	0.00	0.00	0.00	0.00	3.00	3.00	.
R1006	Placebo	10.00	12.00	10.00	12.00	12.00	12.00	12.00	12.00
R1007	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R1008	Placebo	.	.	.	.	.	.	.	.
R1009	Active	.	.	.	.	.	.	.	.
R1010	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R1011	Placebo	20.00	18.00	18.00	15.00	15.00	18.00	18.00	20.00
R1012	Placebo	11.00	15.00	15.00	20.00	20.00	20.00	20.00	20.00
R1013	Placebo	6.00	6.00	6.00	6.00	3.00	3.00	1.00	3.00
R1014	Placebo	.	.	.	.	.	.	.	.
R1015	Active	0.30	0.30	0.30	0.30	0.30	0.30	1.40	0.70
R1016	Active	3.00	8.00	4.00	3.00	6.00	7.00	9.00	3.00
R1017	Active	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00
R1018	Placebo	.	.	.	.	.	.	.	.
R1019	Active	8.00	7.00	6.00	7.00	6.00	6.00	6.00	7.00
R1020	Placebo	1.00	0.00	1.00	1.00	1.00	0.00	.	.
R1021	Placebo	5.00	4.00	4.00	4.00	3.00	4.00	3.00	5.00
R1022	Active	10.00	10.00	15.00	15.00	15.00	15.00	15.00	15.00
R1023	Placebo	.	.	.	.	.	.	.	.
R1024	Active	15.00	15.00	12.00	15.00	15.00	15.00	15.00	15.00
R1025	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R1026	Active	0.00	0.00	3.00	2.00	3.00	5.00	3.00	5.00
R1027	Placebo	.	.	.	.	.	.	.	.
R1028	Placebo	4.00	8.00	6.00	6.00	6.00	10.00	8.00	6.00
R1029	Active	.	.	.	.	.	.	.	.
R1030	Placebo	5.00	4.00	10.00	10.00	10.00	10.00	5.00	1.00
R1031	Active	12.00	10.00	12.00	20.00	7.00	0.00	0.00	0.00
R1032	Active	.	.	.	.	.	.	.	.
R1033	Placebo	.	.	.	.	.	.	.	.
R1034	Placebo	6.00	4.00	4.00	4.00	6.00	6.00	4.00	8.00
R1035	Active	17.00	16.00	17.00	17.00	17.00	16.00	16.00	17.00
R1036	Placebo	.	.	.	.	.	.	.	.
R1037	Active	20.00	20.00	20.00	20.00	20.00	20.00	20.00	0.00
R5001	Placebo	15.00	15.00	15.00	15.00	15.00	15.00	15.00	10.00
R5002	Active	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00
R5003	Placebo	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
R5004	Active	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00
R5005	Placebo	.	.	.	.	.	.	.	.
R5006	Active	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00
R5007	Active	.	.	.	.	.	.	.	.
R5008	Placebo	6.00	6.00	6.00	6.00	6.00	6.00	6.00	6.00
R5009	Placebo	.	.	.	.	.	.	.	.
R5010	Active	.	.	.	.	.	.	.	.
R5011	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R5012	Placebo	.	.	.	.	.	.	.	.
R5013	Active	3.00	2.00	4.00	2.00	4.00	2.00	2.00	6.00

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**Average number of Cigarettes per day  
(USA)**

Subject ID	Group	Week 21	Week 22	Week 23	Week 24	Week 25	Week 26	Week 27	Week 28
R5014	Placebo	.	.	.	.	.	.	.	.
R5015	Placebo	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00
R5016	Placebo	.	.	.	.	.	.	.	.
R5017	Active	.	.	.	.	.	.	.	.
R5018	Active	6.00	6.00	3.00	3.00	4.00	2.00	4.00	5.00
R5019	Placebo	10.00	10.00	.	10.00	10.00	10.00	10.00	10.00
R5020	Active	2.00	2.00	2.00	2.00	5.00	5.00	10.00	10.00
R5021	Placebo	.	.	.	.	.	.	.	.
R5022	Active	2.00	2.00	2.00	2.00	4.00	6.00	8.00	10.00
R5023	Active	4.00	3.00	4.00	4.00	4.00	3.00	3.00	3.00
R5024	Placebo	.	.	.	.	.	.	.	.
R5025	Placebo	.	.	.	.	.	.	.	13.00
R5026	Placebo	.	.	.	.	.	.	.	.
R5027	Active	.	.	.	.	.	.	.	.
R5028	Active	5.00	5.00	5.00	5.00	5.00	5.00	5.00	15.00
R3001	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R3002	Placebo	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R3003	Active	.	.	.	.	.	.	.	.
R3004	Placebo	5.00	4.00	4.00	3.00	4.00	4.00	6.00	3.00
R3005	Placebo	.	.	.	.	.	.	.	.
R3006	Active	1.00	1.00	1.00	1.00	0.00	1.00	1.00	1.00
R3007	Placebo	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
R3008	Placebo	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R3009	Active	.	.	.	.	.	.	.	.
R3010	Placebo	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R3011	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	10.00
R3012	Active	.	.	.	.	.	.	.	.
R3013	Active	0.00	1.00	0.00	0.00	0.00	0.00	0.00	.
R3014	Placebo	.	.	.	.	.	.	.	.
R3015	Placebo	.	.	.	.	.	.	.	.
R3016	Active	2.00	1.00	2.00	3.00	2.00	2.00	3.00	2.00
R3017	Active	.	.	.	.	.	.	.	.
R3018	Placebo	.	.	.	.	.	.	.	.
R3019	Placebo	14.00	15.00	13.00	12.00	12.00	14.00	13.00	13.00
R3020	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R3021	Active	.	.	.	.	.	.	.	.
R3022	Placebo	30.00	30.00	30.00	25.00	30.00	30.00	30.00	30.00
R3023	Placebo	.	.	.	.	.	.	.	.
R3024	Active	.	.	.	.	.	.	.	.
R3025	Placebo	.	.	.	.	.	.	.	.
R3026	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R3027	Active	.	.	.	.	.	.	.	.
R3028	Placebo	5.00	5.00	6.00	5.00	6.00	5.00	6.00	6.00
R3029	Placebo	.	.	.	.	.	.	.	.
R3030	Active	.	.	.	.	.	.	.	.
R3031	Active	3.00	2.00	3.00	3.00	4.00	3.00	4.00	4.00
R3032	Placebo	.	.	.	.	.	.	.	.
R2001	Active	.	.	.	.	.	.	.	.
R2002	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R2003	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

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**Listing 6: User Diary**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(USA)**

Subject ID	Group	Week 21	Week 22	Week 23	Week 24	Week 25	Week 26	Week 27	Week 28
R2004	Placebo	.	.	.	.	.	.	.	.
R2005	Placebo	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R2006	Placebo	.	.	.	.	.	.	.	.
R2007	Placebo	6.00	6.00	6.00	6.00	3.00	0.00	0.00	3.00
R2008	Active	.	.	.	.	.	.	.	.
R2009	Placebo	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R2010	Active	3.00	3.00	2.00	2.00	3.00	3.00	3.00	4.00
R2011	Placebo	10.00	12.00	9.00	12.00	15.00	18.00	11.00	15.00
R2012	Active	2.00	12.00	20.00	10.00	10.00	10.00	10.00	12.00
R2013	Active	10.00	6.00	3.00	0.00	0.00	0.00	1.00	10.00
R2014	Placebo	15.00	15.00	15.00	15.00	15.00	15.00	15.00	15.00
R2015	Active	11.00	11.00	11.00	14.00	12.00	12.00	8.00	8.00
R2016	Placebo	10.00	10.00	10.00	10.00	10.00	10.00	10.00	5.00
R2017	Active	10.00	7.00	4.00	10.00	10.00	10.00	10.00	10.00
R2018	Placebo	.	.	.	.	.	.	.	.
R2019	Placebo	10.00	15.00	10.00	10.00	15.00	15.00	20.00	10.00
R2020	Active	.	.	.	.	.	.	.	.
R2021	Active	2.00	2.00	2.00	2.00	5.00	10.00	10.00	.
R2022	Placebo	5.00	5.00	5.00	5.00	6.00	7.00	8.00	9.00
R2023	Placebo	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R2024	Active	0.00	0.00	0.00	0.00	0.30	1.00	1.00	1.00
R2025	Active	.	.	.	.	.	.	.	.
R2026	Active	20.00	20.00	20.00	20.00	25.00	20.00	25.00	20.00
R2027	Active	30.00	25.00	30.00	40.00	40.00	40.00	40.00	40.00
R2028	Placebo	15.00	15.00	15.00	15.00	20.00	20.00	20.00	20.00
R2029	Placebo	14.00	10.00	14.00	12.00	10.00	12.00	15.00	16.00
R2030	Placebo	.	.	.	.	.	.	.	.
R2031	Placebo	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R2032	Active	.	.	.	.	.	.	.	.
R4001	Placebo	.	.	.	.	.	.	.	.
R4002	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R4003	Placebo	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00
R4004	Active	.	.	.	.	.	.	.	.
R4005	Active	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00
R4006	Placebo	.	.	.	.	.	.	.	.
R4007	Active	15.00	15.00	20.00	25.00	20.00	20.00	20.00	20.00
R4008	Active	18.00	15.00	11.00	15.00	10.00	18.00	10.00	18.00
R4009	Placebo	.	.	.	.	.	.	.	.
R4010	Placebo	.	5.00	5.00	5.00	10.00	10.00	10.00	7.00
R4011	Placebo	25.00	25.00	20.00	20.00	20.00	25.00	25.00	.
R4012	Active	5.00	5.00	6.00	6.00	10.00	10.00	10.00	3.00
R4013	Active	.	.	.	.	.	.	.	.
R4014	Placebo	.	.	.	.	.	.	.	.
R4015	Placebo	16.00	12.00	20.00	12.00	18.00	20.00	20.00	20.00
R4016	Active	9.00	10.00	11.00	10.00	9.00	10.00	9.00	10.00
R4017	Active	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00
R4018	Placebo	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00
R4019	Placebo	7.00	8.00	10.00	10.00	10.00	10.00	10.00	10.00
R4020	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.00
R4021	Placebo	.	.	.	.	.	.	.	.

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**Listing 6: User Diary**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(USA)**

Subject ID	Group	Week 21	Week 22	Week 23	Week 24	Week 25	Week 26	Week 27	Week 28
R4022	Active	.	.	.	.	.	.	.	.
R4023	Placebo	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R4024	Active	.	.	.	.	.	.	.	.
R4025	Active	.	.	.	.	.	.	.	.
R4026	Placebo	6.00	6.00	6.00	6.00	6.00	6.00	6.00	6.00
R4027	Active	2.00	2.00	2.00	2.00	4.00	4.00	5.00	4.00
R4028	Active	25.00	25.00	30.00	30.00	30.00	30.00	30.00	30.00
R4029	Placebo	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R4030	Placebo	.	.	.	.	.	.	.	.
R4031	Placebo	.	.	.	.	.	.	.	.
R4032	Placebo	8.00	10.00	20.00	8.00	12.00	16.00	20.00	20.00
R4033	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R4034	Active	.	.	.	.	.	.	.	.
R4035	Active	15.00	20.00	20.00	18.00	16.00	18.00	20.00	20.00
R4036	Placebo	2.00	2.00	2.00	2.00	2.00	1.00	1.00	2.00
R4037	Placebo	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00
R4038	Placebo	8.00	8.00	8.00	8.00	8.00	8.00	8.00	8.00
R4039	Active	30.00	20.00	18.00	20.00	22.00	18.00	20.00	22.00
R4040	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R4041	Placebo	15.00	20.00	20.00	10.00	10.00	15.00	15.00	15.00
R4042	Active	.	.	.	.	.	.	.	.
R4043	Active	.	.	.	.	.	.	.	.
R4044	Active	.	.	.	.	.	.	.	.
R4045	Placebo	15.00	16.00	16.00	16.00	17.00	17.00	16.00	18.00
R4046	Placebo	.	.	.	.	.	.	.	.
R4047	Placebo	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00
R4048	Active	.	.	.	.	.	.	.	.
R4049	Active	10.00	10.00	15.00	15.00	20.00	20.00	20.00	20.00
R4050	Placebo	11.00	10.00	10.00	11.00	15.00	.	.	.
R4051	Active	2.00	2.00	2.00	2.00	3.00	3.00	3.00	3.00
R4052	Placebo	8.00	10.00	8.00	6.00	8.00	9.00	8.00	9.00
R4053	Active	.	.	.	.	.	.	.	.
R4054	Placebo	25.00	25.00	25.00	25.00	30.00	30.00	30.00	30.00
R4055	Active	10.00	10.00	15.00	15.00	15.00	15.00	15.00	10.00
R4056	Active	.	.	.	.	.	.	.	.
R4057	Active	18.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00
R4058	Placebo	15.00	15.00	20.00	17.00	15.00	15.00	15.00	20.00
R4059	Placebo	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R4060	Placebo	20.00	20.00	20.00	18.00	20.00	20.00	20.00	20.00
R4061	Active	.	.	.	.	.	.	.	.
R4062	Placebo	10.00	10.00	10.00	10.00	12.00	12.00	12.00	12.00
R4063	Active	1.00	0.00	2.00	2.00	0.00	3.00	4.00	4.00
R4064	Placebo	.	.	.	.	.	.	.	.
R4065	Active	0.00	0.00	1.00	1.00	0.00	0.00	0.00	0.00
R4066	Placebo	.	.	.	.	.	.	.	.
R4067	Placebo	.	.	.	.	.	.	.	.
R4068	Active	20.00	20.00	20.00	20.00	20.00	20.00	20.00	20.00
R4069	Active	10.00	10.00	10.00	10.00	10.00	10.00	8.00	8.00
R4070	Placebo	20.00	20.00	20.00	20.00	20.00	20.00	25.00	18.00
R4071	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

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Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Average number of Cigarettes per day  
(USA)**

Subject ID	Group	Week 21	Week 22	Week 23	Week 24	Week 25	Week 26	Week 27	Week 28
R4072	Placebo	16.00	16.00	15.00	16.00	16.00	16.00	16.00	16.00
R4073	Active	.	.	.	.	.	.	.	.
R4074	Placebo	.	.	.	.	.	.	.	.
R4075	Active	.	.	.	.	.	.	.	.
R4076	Placebo	.	.	.	.	.	.	.	.
R4077	Active	.	.	.	.	.	.	.	.
R4078	Placebo	.	.	.	.	.	.	.	.
R4079	Placebo	9.00	9.00	8.00	8.00	9.00	8.00	7.00	9.00
R4080	Active	.	.	.	.	.	.	.	.
R4081	Active	.	.	.	.	.	.	.	.
R4082	Placebo	.	.	.	.	.	.	.	.
R4083	Active	3.00	3.00	2.00	2.00	4.00	3.00	3.00	3.00
R4084	Placebo	.	.	.	.	.	.	.	.
R4085	Active	.	.	.	.	.	.	.	.
R4086	Active	.	.	.	.	.	.	.	.
R4087	Placebo	.	.	.	.	.	.	.	.
R4088	Placebo	.	.	.	.	.	.	.	.
R4089	Placebo	.	.	.	.	.	.	.	.
R4090	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R4091	Active	.	.	.	.	.	.	.	.
R4092	Active	40.00	40.00	40.00	40.00	40.00	40.00	40.00	40.00
R4093	Placebo	8.00	9.00	9.00	8.00	8.00	9.00	9.00	9.00
R4094	Placebo	4.00	4.00	6.00	4.00	6.00	4.00	4.00	6.00
R4095	Active	.	.	.	.	.	.	.	.
R4096	Placebo	7.00	8.00	7.00	9.00	9.00	10.00	8.00	9.00
R4097	Active	10.00	12.00	12.00	12.00	14.00	14.00	12.00	16.00
R4098	Placebo	.	.	.	.	.	.	.	.
R4099	Active	1.00	0.00	0.00	0.00	0.00	0.00	1.00	0.00
R4100	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R4101	Placebo	.	.	.	.	.	.	.	.
R4102	Placebo	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R4103	Placebo	.	.	.	.	.	.	.	.
R4104	Placebo	.	.	.	.	.	.	.	.
R4105	Active	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
R4106	Active	.	.	.	.	.	.	.	.
R4107	Active	8.00	8.00	8.00	8.00	10.00	10.00	10.00	12.00
R4108	Placebo	.	.	.	.	.	.	.	.
R4109	Placebo	.	.	.	.	.	.	.	.
R4110	Active	.	.	.	.	.	.	.	.
R4111	Placebo	.	.	.	.	.	.	.	.
R4112	Active	.	.	.	.	.	.	.	.
R4113	Active	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00
R4114	Placebo	4.00	4.00	0.00	0.00	0.00	0.00	0.00	0.00
R4115	Active	.	.	.	.	.	.	.	.
R4116	Placebo	3.00	3.00	3.00	3.00	2.00	1.00	0.00	0.00
R4117	Active	3.00	6.00	3.00	3.00	3.00	4.00	3.00	3.00
R4118	Placebo	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00
R4119	Placebo	8.00	8.00	7.00	7.00	7.00	.	7.00	7.00
R4120	Active	.	.	.	.	.	.	.	.
R4121	Placebo	.	.	.	.	.	.	.	.

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**Listing 7: User Diary**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Smoked Tobacco Products other than Cigarettes  
(USA)**

Subject ID	Group	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10
R1001	Active	No									
R1002	Placebo	No									
R1003	Active	No	.	.	.	.	.	.	.	.	.
R1004	Placebo	No	No	No	No	No	.	No	No	No	No
R1005	Active	No	.	No							
R1006	Placebo	No	No	No	No	No	.	No	No	No	No
R1007	Active	No									
R1008	Placebo	No	.								
R1009	Active	No	.								
R1010	Active	No									
R1011	Placebo	No									
R1012	Placebo	No									
R1013	Placebo	No									
R1014	Placebo	.	.	.	.	.	.	.	.	.	.
R1015	Active	No									
R1016	Active	No	No	No	No	No	.	No	No	No	No
R1017	Active	No									
R1018	Placebo	No									
R1019	Active	No									
R1020	Placebo	No									
R1021	Placebo	No									
R1022	Active	No	No	No	.	No	No	No	No	No	No
R1023	Placebo	No	No	No	No	No	.	.	.	.	.
R1024	Active	No	No	No	No	.	No	No	No	No	No
R1025	Active	No									
R1026	Active	No									
R1027	Placebo	No	.	.	.	.	.	.	.	.	.
R1028	Placebo	No									
R1029	Active	No	No	No	No	No	.	.	.	.	.
R1030	Placebo	No									
R1031	Active	No									
R1032	Active	No									
R1033	Placebo	No	No	No	No	No	.	.	.	.	.
R1034	Placebo	No									
R1035	Active	No									
R1036	Placebo	No									
R1037	Active	No									
R5001	Placebo	No									
R5002	Active	No									
R5003	Placebo	No									
R5004	Active	No	No	No	No	.	No	No	No	No	No
R5005	Placebo	No	No	No	No	.	.	.	.	.	.
R5006	Active	No									
R5007	Active	.	.	.	.	.	.	.	.	.	.
R5008	Placebo	No	No	No	No	.	No	No	No	No	No
R5009	Placebo	No	No	.	.	.	.	.	.	.	.
R5010	Active	No	No	No	No	No	.	.	.	.	.
R5011	Active	No									
R5012	Placebo	No	No	No	No	.	.	.	.	.	.
R5013	Active	No									

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**Smoked Tobacco Products other than Cigarettes  
(USA)**

Subject ID	Group	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10
R5014	Placebo	No									
R5015	Placebo	No	No	No	No	No	.	.	No	No	No
R5016	Placebo	No	No	No	No	No	No	.	.	.	.
R5017	Active	.	.	.	.	.	.	.	.	.	.
R5018	Active	No	No	No	No	No	.	No	No	No	No
R5019	Placebo	No	No	No	No	No	No	.	No	No	No
R5020	Active	No									
R5021	Placebo	No	No	No	No	No	.	No	No	No	No
R5022	Active	No									
R5023	Active	No	.								
R5024	Placebo	.	.	.	.	.	.	.	.	.	.
R5025	Placebo	No									
R5026	Placebo	.	.	.	.	.	.	.	.	.	.
R5027	Active	No									
R5028	Active	No	.	No	No	No	No	.	No	No	No
R3001	Active	No									
R3002	Placebo	No									
R3003	Active	No	No	No	No	No	.	No	No	No	No
R3004	Placebo	No	No	No	No	No	.	No	No	No	No
R3005	Placebo	No	No	No	No	No	.	No	No	No	No
R3006	Active	No	No	No	No	No	.	No	No	No	No
R3007	Placebo	No									
R3008	Placebo	No									
R3009	Active	No	.	.							
R3010	Placebo	No									
R3011	Active	No	.								
R3012	Active	No	No	.	.	.	.	.	.	.	.
R3013	Active	No	No	No	No	.	No	No	No	No	No
R3014	Placebo	No	No	No	No	.	No	No	No	No	No
R3015	Placebo	.	.	.	.	.	.	.	.	.	.
R3016	Active	No									
R3017	Active	No	No	No	No	.	.	.	.	.	.
R3018	Placebo	No	.								
R3019	Placebo	No	No	No	No	.	No	No	No	No	No
R3020	Active	No	.								
R3021	Active	.	.	.	.	.	.	.	.	.	.
R3022	Placebo	No									
R3023	Placebo	No	No	No	No	.	.	.	.	.	.
R3024	Active	No	.	.	.	.	.	.	.	.	.
R3025	Placebo	No	.								
R3026	Active	No	No	No	No	.	No	No	No	No	No
R3027	Active	No	No	No	No	No	.	No	No	No	.
R3028	Placebo	No	No	No	.	No	No	No	No	No	.
R3029	Placebo	No	No	No	No	No	.	.	.	.	.
R3030	Active	.	.	.	.	.	.	.	.	.	.
R3031	Active	No	No	No	No	.	.	No	No	.	.
R3032	Placebo	.	.	.	.	.	.	.	.	.	.
R2001	Active	.	.	.	.	.	.	.	.	.	.
R2002	Active	No	.								
R2003	Active	No	.								

**CONFIDENTIAL**

**Listing 7: User Diary**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Smoked Tobacco Products other than Cigarettes  
(USA)**

Subject ID	Group	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10
R2004	Placebo	No	No	No	No	No	.	.	.	.	.
R2005	Placebo	No	.								
R2006	Placebo	No	No	No	No	No	.	No	No	No	No
R2007	Placebo	No									
R2008	Active	No	No	No	No	No	.	.	.	.	.
R2009	Placebo	No									
R2010	Active	No									
R2011	Placebo	No	No	No	No	No	.	No	No	No	No
R2012	Active	No									
R2013	Active	No	No	No	No	.	.	No	No	No	No
R2014	Placebo	.	No								
R2015	Active	No	No	No	.	No	No	No	No	No	No
R2016	Placebo	No									
R2017	Active	No									
R2018	Placebo	No									
R2019	Placebo	No	No	No	No	No	No	.	.	.	.
R2020	Active	No	No	No	No	No	.	.	.	.	.
R2021	Active	No									
R2022	Placebo	No									
R2023	Placebo	No									
R2024	Active	No									
R2025	Active	No	.								
R2026	Active	No									
R2027	Active	No									
R2028	Placebo	No									
R2029	Placebo	No									
R2030	Placebo	No	No	.	No	No	.	.	.	.	.
R2031	Placebo	No									
R2032	Active	No	.								
R4001	Placebo	No									
R4002	Active	No									
R4003	Placebo	No									
R4004	Active	No	No	No	.	.	.	.	.	.	.
R4005	Active	No									
R4006	Placebo	No	No	No	.	.	.	.	.	.	.
R4007	Active	No									
R4008	Active	No									
R4009	Placebo	.	.	No	.	No	No	No	No	No	No
R4010	Placebo	No									
R4011	Placebo	No									
R4012	Active	No									
R4013	Active	No	No	No	No	No	.	.	.	.	.
R4014	Placebo	No									
R4015	Placebo	No									
R4016	Active	No									
R4017	Active	No									
R4018	Placebo	No									
R4019	Placebo	No									
R4020	Active	No									
R4021	Placebo	No									

**CONFIDENTIAL**

**Listing 7: User Diary**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Smoked Tobacco Products other than Cigarettes  
(USA)**

<b>Subject ID</b>	<b>Group</b>	<b>Week 1</b>	<b>Week 2</b>	<b>Week 3</b>	<b>Week 4</b>	<b>Week 5</b>	<b>Week 6</b>	<b>Week 7</b>	<b>Week 8</b>	<b>Week 9</b>	<b>Week 10</b>
R4022	Active	No									
R4023	Placebo	No									
R4024	Active	No	No	No	No	No	.	.	.	.	.
R4025	Active	No	No	No	No	No	.	.	.	.	.
R4026	Placebo	No	No	No	No	No	.	No	No	No	No
R4027	Active	No									
R4028	Active	No	No	.	No						
R4029	Placebo	No									
R4030	Placebo	No	.								
R4031	Placebo	No	No	No	.	.	.	.	.	.	.
R4032	Placebo	No									
R4033	Active	No									
R4034	Active	No	No	No	.	.	.	.	.	.	.
R4035	Active	No									
R4036	Placebo	No									
R4037	Placebo	No									
R4038	Placebo	No	No	No	No	No	.	No	No	No	No
R4039	Active	No									
R4040	Active	No									
R4041	Placebo	No									
R4042	Active	No									
R4043	Active	No	No	No	No	.	.	.	.	.	.
R4044	Active	No	.								
R4045	Placebo	No									
R4046	Placebo	No	.								
R4047	Placebo	No									
R4048	Active	No									
R4049	Active	No									
R4050	Placebo	No									
R4051	Active	No									
R4052	Placebo	No									
R4053	Active	No	.	.							
R4054	Placebo	No	No	.	No						
R4055	Active	No									
R4056	Active	No									
R4057	Active	No									
R4058	Placebo	No									
R4059	Placebo	No	No	No	No	.	.	No	No	No	No
R4060	Placebo	No									
R4061	Active	No	No	No	No	.	.	.	.	.	.
R4062	Placebo	No									
R4063	Active	No									
R4064	Placebo	No									
R4065	Active	No									
R4066	Placebo	No	No	No	No	.	.	.	.	.	.
R4067	Placebo	No	No	No	No	.	.	.	.	.	.
R4068	Active	No									
R4069	Active	No	No	.	No						
R4070	Placebo	No									
R4071	Active	No									

**CONFIDENTIAL**

**Listing 7: User Diary**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Smoked Tobacco Products other than Cigarettes  
(USA)**

Subject ID	Group	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10
R4072	Placebo	No									
R4073	Active	.	.	.	.	.	.	.	.	.	.
R4074	Placebo	No	No	No	No	No	.	.	.	.	.
R4075	Active	No									
R4076	Placebo	No	.								
R4077	Active	No									
R4078	Placebo	No	.								
R4079	Placebo	No									
R4080	Active	.	.	.	.	.	.	.	.	.	.
R4081	Active	No	No	No	No	.	.	.	.	.	.
R4082	Placebo	No	No	No	No	.	.	.	.	.	.
R4083	Active	No									
R4084	Placebo	No	.								
R4085	Active	.	.	.	.	.	.	.	.	.	.
R4086	Active	No	No	No	No	No	.	.	.	.	.
R4087	Placebo	No									
R4088	Placebo	No	No	No	No	No	.	.	.	.	.
R4089	Placebo	No									
R4090	Active	No	.	No							
R4091	Active	No									
R4092	Active	No									
R4093	Placebo	No									
R4094	Placebo	No									
R4095	Active	.	.	.	.	.	.	.	.	.	.
R4096	Placebo	No									
R4097	Active	No									
R4098	Placebo	No	No	No	No	.	.	.	.	.	.
R4099	Active	No									
R4100	Active	No									
R4101	Placebo	.	.	.	.	.	.	.	.	.	.
R4102	Placebo	No									
R4103	Placebo	No	No	No	No	.	.	.	.	.	.
R4104	Placebo	.	.	.	.	.	.	.	.	.	.
R4105	Active	No									
R4106	Active	No	.								
R4107	Active	No									
R4108	Placebo	No	No	No	No	.	.	.	.	.	.
R4109	Placebo	No	No	No	No	.	.	.	.	.	.
R4110	Active	No	No	No	No	.	.	.	.	.	.
R4111	Placebo	.	.	.	.	.	.	.	.	.	.
R4112	Active	No	No	No	No	.	.	.	.	.	.
R4113	Active	No									
R4114	Placebo	No									
R4115	Active	No	No	No	No	.	.	.	.	.	.
R4116	Placebo	No	No	No	No	No	.	.	.	.	.
R4117	Active	No									
R4118	Placebo	No									
R4119	Placebo	No	No	.	No						
R4120	Active	No									
R4121	Placebo	.	.	.	.	.	.	.	.	.	.

**CONFIDENTIAL**

**Listing 7: User Diary**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Smoked Tobacco Products other than Cigarettes  
(USA)**

Subject ID	Group	Week 11	Week 12	Week 13	Week 14	Week 15	Week 16	Week 17	Week 18	Week 19	Week 20
R1001	Active	No									
R1002	Placebo	No									
R1003	Active	.	.	.	.	.	.	.	.	.	.
R1004	Placebo	No									
R1005	Active	No									
R1006	Placebo	No									
R1007	Active	No									
R1008	Placebo	.	.	.	.	.	.	.	.	.	.
R1009	Active	.	.	.	.	.	.	.	.	.	.
R1010	Active	No									
R1011	Placebo	No									
R1012	Placebo	No									
R1013	Placebo	No									
R1014	Placebo	.	.	.	.	.	.	.	.	.	.
R1015	Active	No									
R1016	Active	No									
R1017	Active	No									
R1018	Placebo	.	.	.	.	.	.	.	.	.	.
R1019	Active	No									
R1020	Placebo	No									
R1021	Placebo	No									
R1022	Active	No									
R1023	Placebo	.	.	.	.	.	.	.	.	.	.
R1024	Active	No									
R1025	Active	No									
R1026	Active	No									
R1027	Placebo	.	.	.	.	.	.	.	.	.	.
R1028	Placebo	No									
R1029	Active	.	.	.	.	.	.	.	.	.	.
R1030	Placebo	No									
R1031	Active	No									
R1032	Active	No	No	No	No	No	No	.	.	.	.
R1033	Placebo	.	.	.	.	.	.	.	.	.	.
R1034	Placebo	No									
R1035	Active	No									
R1036	Placebo	.	.	.	.	.	.	.	.	.	.
R1037	Active	No									
R5001	Placebo	No									
R5002	Active	No									
R5003	Placebo	No									
R5004	Active	No									
R5005	Placebo	.	.	.	.	.	.	.	.	.	.
R5006	Active	No									
R5007	Active	.	.	.	.	.	.	.	.	.	.
R5008	Placebo	No									
R5009	Placebo	.	.	.	.	.	.	.	.	.	.
R5010	Active	.	.	.	.	.	.	.	.	.	.
R5011	Active	No									
R5012	Placebo	.	.	.	.	.	.	.	.	.	.
R5013	Active	No									

**CONFIDENTIAL**

**Listing 7: User Diary**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Smoked Tobacco Products other than Cigarettes  
(USA)**

Subject ID	Group	Week 11	Week 12	Week 13	Week 14	Week 15	Week 16	Week 17	Week 18	Week 19	Week 20
R5014	Placebo	No	.	.	.						
R5015	Placebo	No									
R5016	Placebo	.	.	.	.	.	.	.	.	.	.
R5017	Active	.	.	.	.	.	.	.	.	.	.
R5018	Active	No									
R5019	Placebo	No									
R5020	Active	No									
R5021	Placebo	No	No	No	No	No	No	.	.	.	.
R5022	Active	No									
R5023	Active	No									
R5024	Placebo	.	.	.	.	.	.	.	.	.	.
R5025	Placebo	No	.	.							
R5026	Placebo	.	.	.	.	.	.	.	.	.	.
R5027	Active	No	No	No	No	No	No	.	.	.	.
R5028	Active	No	No	No	No	No	No	.	.	.	No
R3001	Active	No									
R3002	Placebo	No									
R3003	Active	No	No	No	No	No	No	.	.	.	.
R3004	Placebo	No									
R3005	Placebo	No	No	No	No	.	.	.	.	.	.
R3006	Active	No									
R3007	Placebo	No									
R3008	Placebo	No									
R3009	Active	.	.	.	.	.	.	.	.	.	.
R3010	Placebo	No									
R3011	Active	.	.	.	.	.	.	No	No	No	No
R3012	Active	.	.	.	.	.	.	.	.	.	.
R3013	Active	No									
R3014	Placebo	.	.	.	.	.	.	.	.	.	.
R3015	Placebo	.	.	.	.	.	.	.	.	.	.
R3016	Active	No									
R3017	Active	.	.	.	.	.	.	.	.	.	.
R3018	Placebo	No	.	.	.						
R3019	Placebo	No									
R3020	Active	.	.	.	.	.	.	No	No	No	No
R3021	Active	.	.	.	.	.	.	.	.	.	.
R3022	Placebo	No	No	No	No	No	No	.	.	No	No
R3023	Placebo	.	.	.	.	.	.	.	.	.	.
R3024	Active	.	.	.	.	.	.	.	.	.	.
R3025	Placebo	.	.	.	.	.	.	.	.	.	.
R3026	Active	No									
R3027	Active	.	.	.	.	.	.	.	.	.	.
R3028	Placebo	.	.	.	.	.	.	No	No	No	No
R3029	Placebo	.	.	.	.	.	.	.	.	.	.
R3030	Active	.	.	.	.	.	.	.	.	.	.
R3031	Active	.	.	.	.	.	.	.	.	.	No
R3032	Placebo	.	.	.	.	.	.	.	.	.	.
R2001	Active	.	.	.	.	.	.	.	.	.	.
R2002	Active	No									
R2003	Active	No	No	No	No	.	No	No	No	No	No

**CONFIDENTIAL**

**Listing 7: User Diary**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Smoked Tobacco Products other than Cigarettes  
(USA)**

Subject ID	Group	Week 11	Week 12	Week 13	Week 14	Week 15	Week 16	Week 17	Week 18	Week 19	Week 20
R2004	Placebo	.	.	.	.	.	.	.	.	.	.
R2005	Placebo	No									
R2006	Placebo	No	.	.	.						
R2007	Placebo	No									
R2008	Active	.	.	.	.	.	.	.	.	.	.
R2009	Placebo	No									
R2010	Active	No									
R2011	Placebo	No									
R2012	Active	No									
R2013	Active	.	.	.	.	.	No	No	No	No	No
R2014	Placebo	No									
R2015	Active	No									
R2016	Placebo	No	.	No	No						
R2017	Active	No									
R2018	Placebo	.	.	.	.	.	No	No	No	No	No
R2019	Placebo	No									
R2020	Active	.	.	.	.	.	No	No	No	No	No
R2021	Active	No									
R2022	Placebo	No	No	No	No	No	.	.	.	No	No
R2023	Placebo	No									
R2024	Active	No	No	No	No	No	No	.	No	No	No
R2025	Active	.	.	.	.	.	.	.	.	.	.
R2026	Active	No									
R2027	Active	No									
R2028	Placebo	No									
R2029	Placebo	No									
R2030	Placebo	.	.	.	.	.	.	.	.	.	.
R2031	Placebo	No									
R2032	Active	.	.	.	.	.	.	.	.	.	.
R4001	Placebo	No	No	No	No	No	.	.	.	.	.
R4002	Active	No	No	No	No	.	No	No	No	No	No
R4003	Placebo	No									
R4004	Active	.	.	.	.	.	.	.	.	.	.
R4005	Active	No	No	No	No	.	No	No	No	No	No
R4006	Placebo	.	.	.	.	.	.	.	.	.	.
R4007	Active	No									
R4008	Active	No									
R4009	Placebo	No	No	No	No	No	No	.	.	.	.
R4010	Placebo	No									
R4011	Placebo	No									
R4012	Active	No									
R4013	Active	.	.	.	.	.	.	.	.	.	.
R4014	Placebo	No	No	No	No	No	No	.	.	.	.
R4015	Placebo	No									
R4016	Active	No									
R4017	Active	No									
R4018	Placebo	No									
R4019	Placebo	No									
R4020	Active	No									
R4021	Placebo	No	No	No	No	No	No	.	.	.	.

**CONFIDENTIAL**

**Listing 7: User Diary**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Smoked Tobacco Products other than Cigarettes  
(USA)**

Subject ID	Group	Week 11	Week 12	Week 13	Week 14	Week 15	Week 16	Week 17	Week 18	Week 19	Week 20
R4022	Active	No	No	No	No	No	No	.	.	.	.
R4023	Placebo	No									
R4024	Active	.	.	.	.	.	.	.	.	.	.
R4025	Active	.	.	.	.	.	.	.	.	.	.
R4026	Placebo	No									
R4027	Active	No									
R4028	Active	No	No	No	No	No	.	No	No	No	No
R4029	Placebo	No									
R4030	Placebo	.	.	.	.	.	.	.	.	.	.
R4031	Placebo	.	.	.	.	.	.	.	.	.	.
R4032	Placebo	No									
R4033	Active	No	No	No	No	No	.	No	No	No	No
R4034	Active	.	.	.	.	.	.	.	.	.	.
R4035	Active	No	No	No	No	.	.	No	No	No	No
R4036	Placebo	No									
R4037	Placebo	No									
R4038	Placebo	No									
R4039	Active	No									
R4040	Active	No									
R4041	Placebo	No									
R4042	Active	No									
R4043	Active	.	.	.	.	.	.	.	.	.	.
R4044	Active	.	.	.	.	.	.	.	.	.	.
R4045	Placebo	No									
R4046	Placebo	.	.	.	.	.	.	.	.	.	.
R4047	Placebo	No									
R4048	Active	No	.	.	.	.	.	.	.	.	.
R4049	Active	No									
R4050	Placebo	No									
R4051	Active	No									
R4052	Placebo	No									
R4053	Active	.	.	.	.	.	.	.	.	.	.
R4054	Placebo	No									
R4055	Active	No									
R4056	Active	No	No	No	No	No	.	.	.	.	.
R4057	Active	No									
R4058	Placebo	No									
R4059	Placebo	No									
R4060	Placebo	No									
R4061	Active	.	.	.	.	.	.	.	.	.	.
R4062	Placebo	No									
R4063	Active	No									
R4064	Placebo	No	No	No	No	No	No	.	.	.	.
R4065	Active	No									
R4066	Placebo	.	.	.	.	.	.	.	.	.	.
R4067	Placebo	.	.	.	.	.	.	.	.	.	.
R4068	Active	No									
R4069	Active	No									
R4070	Placebo	No									
R4071	Active	No									

**CONFIDENTIAL**

**Listing 7: User Diary**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Smoked Tobacco Products other than Cigarettes  
(USA)**

Subject ID	Group	Week 11	Week 12	Week 13	Week 14	Week 15	Week 16	Week 17	Week 18	Week 19	Week 20
R4072	Placebo	No									
R4073	Active	.	.	.	.	.	.	.	.	.	.
R4074	Placebo	.	.	.	.	.	.	.	.	.	.
R4075	Active	No	No	No	No	No	No	.	.	.	.
R4076	Placebo	.	.	.	.	.	.	.	.	.	.
R4077	Active	No	No	No	No	No	No	.	.	.	.
R4078	Placebo	.	.	.	.	.	.	.	.	.	.
R4079	Placebo	No									
R4080	Active	.	.	.	.	.	.	.	.	.	.
R4081	Active	.	.	.	.	.	.	.	.	.	.
R4082	Placebo	.	.	.	.	.	.	.	.	.	.
R4083	Active	No									
R4084	Placebo	.	.	.	.	.	.	.	.	.	.
R4085	Active	.	.	.	.	.	.	.	.	.	.
R4086	Active	.	.	.	.	.	.	.	.	.	.
R4087	Placebo	No	No	No	.	.	.	.	.	.	.
R4088	Placebo	.	.	.	.	.	.	.	.	.	.
R4089	Placebo	No	No	No	No	No	No	.	.	.	.
R4090	Active	No									
R4091	Active	No	No	No	No	No	No	.	.	.	.
R4092	Active	No									
R4093	Placebo	No									
R4094	Placebo	No									
R4095	Active	.	.	.	.	.	.	.	.	.	.
R4096	Placebo	No									
R4097	Active	No									
R4098	Placebo	.	.	.	.	.	.	.	.	.	.
R4099	Active	No	No	No	.	No	No	No	No	No	No
R4100	Active	No									
R4101	Placebo	.	.	.	.	.	.	.	.	.	.
R4102	Placebo	No									
R4103	Placebo	.	.	.	.	.	.	.	.	.	.
R4104	Placebo	.	.	.	.	.	.	.	.	.	.
R4105	Active	No									
R4106	Active	.	.	.	.	.	.	.	.	.	.
R4107	Active	No									
R4108	Placebo	.	.	.	.	.	.	.	.	.	.
R4109	Placebo	.	.	.	.	.	.	.	.	.	.
R4110	Active	.	.	.	.	.	.	.	.	.	.
R4111	Placebo	.	.	.	.	.	.	.	.	.	.
R4112	Active	.	.	.	.	.	.	.	.	.	.
R4113	Active	No									
R4114	Placebo	No									
R4115	Active	.	.	.	.	.	.	.	.	.	.
R4116	Placebo	.	.	.	.	.	.	No	No	No	No
R4117	Active	No									
R4118	Placebo	No									
R4119	Placebo	No									
R4120	Active	No	No	No	No	No	No	.	.	.	.
R4121	Placebo	.	.	.	.	.	.	.	.	.	.

**CONFIDENTIAL**

**Listing 7: User Diary**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Smoked Tobacco Products other than Cigarettes  
(USA)**

Subject ID	Group	Week 21	Week 22	Week 23	Week 24	Week 25	Week 26	Week 27	Week 28
R1001	Active	No							
R1002	Placebo	No							
R1003	Active	.	.	.	.	.	.	.	.
R1004	Placebo	No							
R1005	Active	No	.						
R1006	Placebo	No							
R1007	Active	No							
R1008	Placebo	.	.	.	.	.	.	.	.
R1009	Active	.	.	.	.	.	.	.	.
R1010	Active	No							
R1011	Placebo	No							
R1012	Placebo	No							
R1013	Placebo	No							
R1014	Placebo	.	.	.	.	.	.	.	.
R1015	Active	No							
R1016	Active	No							
R1017	Active	No							
R1018	Placebo	.	.	.	.	.	.	.	.
R1019	Active	No							
R1020	Placebo	No	No	No	No	No	No	.	.
R1021	Placebo	No							
R1022	Active	No							
R1023	Placebo	.	.	.	.	.	.	.	.
R1024	Active	No							
R1025	Active	No							
R1026	Active	No							
R1027	Placebo	.	.	.	.	.	.	.	.
R1028	Placebo	No							
R1029	Active	.	.	.	.	.	.	.	.
R1030	Placebo	No							
R1031	Active	No							
R1032	Active	.	.	.	.	.	.	.	.
R1033	Placebo	.	.	.	.	.	.	.	.
R1034	Placebo	No							
R1035	Active	No							
R1036	Placebo	.	.	.	.	.	.	.	.
R1037	Active	No							
R5001	Placebo	No							
R5002	Active	No							
R5003	Placebo	No							
R5004	Active	No							
R5005	Placebo	.	.	.	.	.	.	.	.
R5006	Active	No							
R5007	Active	.	.	.	.	.	.	.	.
R5008	Placebo	No							
R5009	Placebo	.	.	.	.	.	.	.	.
R5010	Active	.	.	.	.	.	.	.	.
R5011	Active	No							
R5012	Placebo	.	.	.	.	.	.	.	.
R5013	Active	No							

**CONFIDENTIAL**

**Listing 7: User Diary**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials

**Smoked Tobacco Products other than Cigarettes  
(USA)**

Subject ID	Group	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
R5014	Placebo	.	.	.	.	.	.	.	.
R5015	Placebo	No							
R5016	Placebo	.	.	.	.	.	.	.	.
R5017	Active	.	.	.	.	.	.	.	.
R5018	Active	No							
R5019	Placebo	No							
R5020	Active	No							
R5021	Placebo	.	.	.	.	.	.	.	.
R5022	Active	No							
R5023	Active	No							
R5024	Placebo	.	.	.	.	.	.	.	.
R5025	Placebo	.	.	.	.	.	.	.	No
R5026	Placebo	.	.	.	.	.	.	.	.
R5027	Active	.	.	.	.	.	.	.	.
R5028	Active	No							
R3001	Active	No							
R3002	Placebo	No							
R3003	Active	.	.	.	.	.	.	.	.
R3004	Placebo	No							
R3005	Placebo	.	.	.	.	.	.	.	.
R3006	Active	No							
R3007	Placebo	No	.						
R3008	Placebo	No							
R3009	Active	.	.	.	.	.	.	.	.
R3010	Placebo	No							
R3011	Active	No							
R3012	Active	.	.	.	.	.	.	.	.
R3013	Active	No							
R3014	Placebo	.	.	.	.	.	.	.	.
R3015	Placebo	.	.	.	.	.	.	.	.
R3016	Active	No							
R3017	Active	.	.	.	.	.	.	.	.
R3018	Placebo	.	.	.	.	.	.	.	.
R3019	Placebo	No							
R3020	Active	No							
R3021	Active	.	.	.	.	.	.	.	.
R3022	Placebo	No							
R3023	Placebo	.	.	.	.	.	.	.	.
R3024	Active	.	.	.	.	.	.	.	.
R3025	Placebo	.	.	.	.	.	.	.	.
R3026	Active	No							
R3027	Active	.	.	.	.	.	.	.	.
R3028	Placebo	No							
R3029	Placebo	.	.	.	.	.	.	.	.
R3030	Active	.	.	.	.	.	.	.	.
R3031	Active	No							
R3032	Placebo	.	.	.	.	.	.	.	.
R2001	Active	.	.	.	.	.	.	.	.
R2002	Active	No							
R2003	Active	No	.						

**CONFIDENTIAL**

**Listing 7: User Diary**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Smoked Tobacco Products other than Cigarettes  
(USA)**

Subject ID	Group	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
R2004	Placebo	.	.	.	.	.	.	.	.
R2005	Placebo	No							
R2006	Placebo	.	.	.	.	.	.	.	.
R2007	Placebo	No							
R2008	Active	.	.	.	.	.	.	.	.
R2009	Placebo	No							
R2010	Active	No							
R2011	Placebo	No							
R2012	Active	No							
R2013	Active	No							
R2014	Placebo	No							
R2015	Active	No							
R2016	Placebo	No							
R2017	Active	No							
R2018	Placebo	.	.	.	.	.	.	.	.
R2019	Placebo	No							
R2020	Active	.	.	.	.	.	.	.	.
R2021	Active	No	.						
R2022	Placebo	No							
R2023	Placebo	No							
R2024	Active	No							
R2025	Active	.	.	.	.	.	.	.	.
R2026	Active	No							
R2027	Active	No							
R2028	Placebo	No							
R2029	Placebo	No							
R2030	Placebo	.	.	.	.	.	.	.	.
R2031	Placebo	No							
R2032	Active	.	.	.	.	.	.	.	.
R4001	Placebo	.	.	.	.	.	.	.	.
R4002	Active	No							
R4003	Placebo	No							
R4004	Active	.	.	.	.	.	.	.	.
R4005	Active	No							
R4006	Placebo	.	.	.	.	.	.	.	.
R4007	Active	No							
R4008	Active	No							
R4009	Placebo	.	.	.	.	.	.	.	.
R4010	Placebo	No							
R4011	Placebo	No	.						
R4012	Active	No							
R4013	Active	.	.	.	.	.	.	.	.
R4014	Placebo	.	.	.	.	.	.	.	.
R4015	Placebo	No							
R4016	Active	No							
R4017	Active	No							
R4018	Placebo	No							
R4019	Placebo	No							
R4020	Active	No							
R4021	Placebo	.	.	.	.	.	.	.	.

**CONFIDENTIAL**

**Listing 7: User Diary**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Smoked Tobacco Products other than Cigarettes  
(USA)**

Subject ID	Group	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
R4022	Active	.	.	.	.	.	.	.	.
R4023	Placebo	No							
R4024	Active	.	.	.	.	.	.	.	.
R4025	Active	.	.	.	.	.	.	.	.
R4026	Placebo	No							
R4027	Active	No							
R4028	Active	No							
R4029	Placebo	No							
R4030	Placebo	.	.	.	.	.	.	.	.
R4031	Placebo	.	.	.	.	.	.	.	.
R4032	Placebo	No							
R4033	Active	No							
R4034	Active	.	.	.	.	.	.	.	.
R4035	Active	No							
R4036	Placebo	No							
R4037	Placebo	No							
R4038	Placebo	No							
R4039	Active	No							
R4040	Active	No							
R4041	Placebo	No							
R4042	Active	.	.	.	.	.	.	.	.
R4043	Active	.	.	.	.	.	.	.	.
R4044	Active	.	.	.	.	.	.	.	.
R4045	Placebo	No							
R4046	Placebo	.	.	.	.	.	.	.	.
R4047	Placebo	No							
R4048	Active	.	.	.	.	.	.	.	.
R4049	Active	No							
R4050	Placebo	No	No	No	No	No	.	.	.
R4051	Active	No							
R4052	Placebo	No							
R4053	Active	.	.	.	.	.	.	.	.
R4054	Placebo	No							
R4055	Active	No							
R4056	Active	.	.	.	.	.	.	.	.
R4057	Active	No							
R4058	Placebo	No							
R4059	Placebo	No							
R4060	Placebo	No							
R4061	Active	.	.	.	.	.	.	.	.
R4062	Placebo	No							
R4063	Active	No							
R4064	Placebo	.	.	.	.	.	.	.	.
R4065	Active	No							
R4066	Placebo	.	.	.	.	.	.	.	.
R4067	Placebo	.	.	.	.	.	.	.	.
R4068	Active	No							
R4069	Active	No							
R4070	Placebo	No							
R4071	Active	No							

**CONFIDENTIAL**

**Listing 7: User Diary**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Smoked Tobacco Products other than Cigarettes  
(USA)**

Subject ID	Group	Week 21	Week 22	Week 23	Week 24	Week 25	Week 26	Week 27	Week 28
R4072	Placebo	No							
R4073	Active	.	.	.	.	.	.	.	.
R4074	Placebo	.	.	.	.	.	.	.	.
R4075	Active	.	.	.	.	.	.	.	.
R4076	Placebo	.	.	.	.	.	.	.	.
R4077	Active	.	.	.	.	.	.	.	.
R4078	Placebo	.	.	.	.	.	.	.	.
R4079	Placebo	No							
R4080	Active	.	.	.	.	.	.	.	.
R4081	Active	.	.	.	.	.	.	.	.
R4082	Placebo	.	.	.	.	.	.	.	.
R4083	Active	No							
R4084	Placebo	.	.	.	.	.	.	.	.
R4085	Active	.	.	.	.	.	.	.	.
R4086	Active	.	.	.	.	.	.	.	.
R4087	Placebo	.	.	.	.	.	.	.	.
R4088	Placebo	.	.	.	.	.	.	.	.
R4089	Placebo	.	.	.	.	.	.	.	.
R4090	Active	No							
R4091	Active	.	.	.	.	.	.	.	.
R4092	Active	No							
R4093	Placebo	No							
R4094	Placebo	No							
R4095	Active	.	.	.	.	.	.	.	.
R4096	Placebo	No							
R4097	Active	No							
R4098	Placebo	.	.	.	.	.	.	.	.
R4099	Active	No	No	No	No	.	No	No	No
R4100	Active	No							
R4101	Placebo	.	.	.	.	.	.	.	.
R4102	Placebo	No							
R4103	Placebo	.	.	.	.	.	.	.	.
R4104	Placebo	.	.	.	.	.	.	.	.
R4105	Active	No							
R4106	Active	.	.	.	.	.	.	.	.
R4107	Active	No							
R4108	Placebo	.	.	.	.	.	.	.	.
R4109	Placebo	.	.	.	.	.	.	.	.
R4110	Active	.	.	.	.	.	.	.	.
R4111	Placebo	.	.	.	.	.	.	.	.
R4112	Active	.	.	.	.	.	.	.	.
R4113	Active	No							
R4114	Placebo	No							
R4115	Active	.	.	.	.	.	.	.	.
R4116	Placebo	No							
R4117	Active	No	.	No	No	No	No	No	No
R4118	Placebo	No							
R4119	Placebo	No	No	No	No	.	No	No	No
R4120	Active	.	.	.	.	.	.	.	.
R4121	Placebo	.	.	.	.	.	.	.	.

**CONFIDENTIAL**

**Listing 8: Efficacy Assessments**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")

on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Reduced or Stopped Smoking  
(Serbia)**

Subject ID	Group	Reduced smoking by 50% week 12	Stopped week 12	Reduced smoking weeks 9-12	Stopped by 50% week 24	Stopped week 24	Stopped weeks 21-24
1001	Placebo	No	No	No	No	No	No
1002	Placebo	No	No	No	Yes	No	No
1003	Active	No	No	No	Yes	No	No
1004	Active	No	No	No	.	.	.
1005	Active	Yes	No	No	Yes	No	No
1006	Placebo	No	No	No	No	No	No
1007	Active	.	.	.	.	.	.
1008	Active	Yes	No	No	Yes	No	No
1009	Placebo	No	No	No	Yes	No	No
1010	Placebo	No	No	No	No	No	No
1011	Active	No	No	No	No	No	No
1012	Placebo	No	No	No	No	No	No
1013	Active	No	No	No	No	No	No
1014	Active	No	No	No	No	No	No
1015	Active	No	No	No	.	.	.
1016	Placebo	No	No	No	Yes	No	No
1017	Placebo	No	No	No	.	.	.
1018	Placebo	.	.	.	.	.	.
1019	Active	No	No	No	No	No	No
1020	Placebo	No	No	No	.	.	.
1021	Active	No	No	No	.	.	.
1022	Placebo	.	.	.	.	.	.
1023	Active	Yes	No	No	Yes	No	No
1024	Placebo	.	.	.	.	.	.
1025	Placebo	No	No	No	No	No	No
1026	Placebo	.	.	.	.	.	.
1027	Placebo	No	No	No	No	No	No
1028	Active	No	No	No	No	No	No
1029	Active	No	No	No	.	.	.
1030	Active	No	No	No	Yes	No	No
1031	Active	No	No	No	No	Yes	No
1032	Active	.	.	.	.	.	.
1033	Placebo	No	No	No	No	No	No
1034	Active	.	.	.	.	.	.
1035	Placebo	No	No	No	No	No	No
1036	Placebo	.	.	.	.	.	.
1037	Placebo	No	No	No	Yes	No	No
1038	Active	No	No	No	Yes	Yes	Yes
1039	Placebo	.	.	.	.	.	.
1040	Active	.	.	.	.	.	.
1041	Placebo	No	No	No	.	.	.
1042	Active	No	No	No	.	.	.
1043	Placebo	No	No	No	No	No	No
1044	Active	.	.	.	.	.	.
1045	Active	.	.	.	.	.	.
1046	Placebo	No	No	No	.	.	.
1047	Active	No	No	No	.	.	.
1048	Placebo	No	No	No	.	.	.
1049	Placebo	No	No	No	.	.	.
1050	Active	Yes	No	No	.	.	.

**CONFIDENTIAL**

**Listing 8: Efficacy Assessments**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials

**Reduced or Stopped Smoking  
(Serbia)**

Subject ID	Group	Reduced smoking by 50% week 12	Stopped week 12	Reduced smoking weeks 9-12	Stopped by 50% week 24	Stopped week 24	Stopped weeks 21-24
1205	Placebo	No	No	No	Yes	No	No
1206	Placebo	.	.	.	.	.	.
1207	Active	.	.	.	.	.	.
1208	Active	Yes	No	No	.	.	.
1209	Active	No	No	No	.	.	.
1210	Placebo	No	No	No	Yes	No	No
1211	Active	No	No	No	.	.	.
1212	Active	Yes	No	No	Yes	No	No
1213	Placebo	No	No	No	.	.	.
1214	Placebo	Yes	No	No	Yes	No	No
1215	Active	No	No	No	No	No	No
1216	Placebo	Yes	No	No	Yes	No	No
1217	Active	No	No	No	.	.	.
1218	Active	.	.	.	.	.	.
1219	Active	.	.	.	.	.	.
1220	Placebo	No	No	No	Yes	No	No
1221	Placebo	No	No	No	.	.	.
1222	Placebo	No	No	No	.	.	.
1223	Active	No	No	No	No	No	No
1224	Placebo	No	No	No	Yes	No	No
1225	Active	Yes	No	No	.	.	.
1226	Placebo	No	No	No	Yes	No	No
1227	Active	Yes	No	No	.	.	.
1228	Placebo	Yes	No	No	.	.	.
1229	Placebo	No	No	No	.	.	.
1230	Placebo	No	No	No	Yes	No	No
1231	Placebo	No	No	No	No	No	No
1232	Active	.	.	.	.	.	.
1233	Active	Yes	No	No	Yes	No	No
1234	Active	No	No	No	.	.	.
1235	Active	Yes	No	No	Yes	No	No
1236	Active	.	.	.	.	.	.
1237	Placebo	No	No	No	Yes	No	No
1238	Active	No	No	No	Yes	No	No
1239	Placebo	No	No	No	Yes	No	No
1240	Placebo	Yes	No	No	Yes	No	No
1241	Placebo	.	.	.	.	.	.
1242	Active	Yes	No	No	Yes	No	No
1243	Placebo	Yes	No	No	Yes	No	No
1244	Active	Yes	No	No	Yes	No	No
1245	Placebo	Yes	No	No	Yes	No	No
1246	Active	Yes	No	No	Yes	No	No
1247	Placebo	No	No	No	Yes	No	No
1325	Placebo	No	No	No	Yes	Yes	Yes
1326	Placebo	No	No	No	Yes	No	No
1327	Active	No	No	No	Yes	No	No
1328	Active	No	No	No	Yes	No	No
1329	Active	No	No	No	Yes	No	No
1330	Placebo	No	No	No	Yes	No	No
1331	Active	No	No	No	Yes	No	No

**CONFIDENTIAL**

**Listing 8: Efficacy Assessments**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")

on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Reduced or Stopped Smoking  
(Serbia)**

Subject ID	Group	Reduced smoking by 50% week 12	Stopped week 12	Reduced smoking weeks 9-12	Stopped by 50% week 24	Stopped week 24	Stopped weeks 21-24
1332	Active	No	No	No	Yes	No	No
1333	Placebo	No	No	No	Yes	No	No
1334	Placebo	No	No	No	Yes	No	No
1335	Active	No	No	No	Yes	No	No
1336	Placebo	No	No	No	Yes	No	No
1337	Active	No	No	No	Yes	No	No
1338	Active	No	No	No	Yes	No	No
1339	Active	No	No	No	Yes	No	No
1340	Placebo	No	No	No	Yes	No	No
1341	Placebo	No	No	No	Yes	No	No
1342	Placebo	No	No	No	No	No	No
1343	Active	No	No	No	Yes	No	No
1344	Placebo	No	No	No	Yes	No	No
1345	Active	No	No	No	Yes	No	No
1346	Placebo	No	No	No	Yes	No	No
1347	Active	No	No	No	No	No	No
1348	Placebo	No	No	No	No	No	No
1349	Placebo	No	No	No	Yes	No	No
2001	Placebo	No	No	No	Yes	No	No
2002	Placebo	No	No	No	Yes	No	No
2003	Active	Yes	No	No	Yes	No	No
2004	Active	No	No	No	No	No	No
2005	Active	No	No	No	No	No	No
2006	Placebo	No	No	No	No	No	No
2007	Active	Yes	No	No	No	No	No
2008	Active	No	No	No	No	No	No
2009	Placebo	No	No	No	No	No	No
2010	Placebo	Yes	No	No	Yes	No	No
2011	Active	No	No	No	No	No	No
2012	Placebo	No	No	No	No	No	No
2013	Active	No	No	No	Yes	No	No
2014	Active	No	No	No	No	No	No
2015	Active	No	No	No	No	No	No
2016	Placebo	No	No	No	Yes	No	No
2017	Placebo	No	No	No	No	No	No
2018	Placebo	No	No	No	No	No	No
2019	Active	No	No	No	Yes	No	No
2020	Placebo	No	No	No	No	No	No
2021	Active	No	No	No	Yes	No	No
2022	Placebo	Yes	No	No	Yes	No	No
2023	Active	Yes	No	No	No	No	No
2024	Placebo	No	No	No	Yes	No	No
2025	Placebo	No	No	No	Yes	No	No
2026	Placebo	No	No	No	Yes	No	No
2027	Placebo	No	No	No	Yes	No	No
2028	Active	Yes	No	No	Yes	No	No
2029	Active	No	No	No	Yes	No	No
2030	Active	No	No	No	Yes	No	No
2031	Active	No	No	No	Yes	No	No
2032	Active	No	No	No	Yes	No	No

**CONFIDENTIAL**

**Listing 8: Efficacy Assessments**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")

on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Reduced or Stopped Smoking  
(Serbia)**

Subject ID	Group	Reduced smoking by 50% week 12	Stopped week 12	Reduced smoking weeks 9-12	Stopped by 50% week 24	Stopped week 24	Stopped weeks 21-24
2033	Placebo	No	No	No	Yes	No	No
2034	Active	No	No	No	Yes	No	No
2035	Placebo	No	No	No	Yes	No	No
2036	Placebo	No	No	No	Yes	No	No
2037	Placebo	No	No	No	.	.	.
2038	Active	No	No	No	.	.	.
2039	Placebo	No	No	No	Yes	No	No
2040	Active	No	No	No	No	No	No
2041	Placebo	No	No	No	.	.	.
2042	Active	No	No	No	Yes	No	No
2043	Placebo	No	No	No	.	.	.
2044	Active	No	No	No	Yes	No	No
2045	Active	No	No	No	Yes	No	No
2046	Placebo	No	No	No	No	No	No
2047	Active	No	No	No	Yes	No	No
2048	Placebo	Yes	No	No	Yes	No	No
2049	Placebo	Yes	No	No	Yes	No	No
2050	Active	No	No	No	Yes	No	No
2205	Active	No	No	No	Yes	No	No
2206	Placebo	No	No	No	Yes	No	No
2207	Placebo	No	No	No	Yes	No	No
2208	Active	No	No	No	Yes	No	No
2209	Active	No	No	No	Yes	No	No
2210	Placebo	No	No	No	Yes	No	No
2211	Placebo	Yes	No	No	Yes	No	No
2212	Placebo	No	No	No	Yes	No	No
2213	Active	No	No	No	Yes	No	No
2214	Active	No	No	No	Yes	No	No
2215	Active	No	No	No	Yes	No	No
2216	Placebo	No	No	No	Yes	No	No
2217	Active	No	No	No	Yes	No	No
2218	Placebo	No	No	No	Yes	No	No
2219	Active	No	No	No	Yes	No	No
2220	Placebo	No	No	No	Yes	No	No
2221	Placebo	No	No	No	Yes	No	No
2222	Active	No	No	No	Yes	No	No
2223	Placebo	No	No	No	Yes	No	No
2224	Placebo	No	No	No	Yes	No	No
2225	Placebo	No	No	No	Yes	No	No
2226	Active	Yes	No	No	Yes	No	No
2227	Active	Yes	No	No	Yes	No	No
2228	Active	No	No	No	Yes	No	No
2229	Placebo	No	No	No	Yes	No	No
2230	Active	No	No	No	Yes	No	No
2231	Active	No	No	No	Yes	No	No
2232	Placebo	No	No	No	Yes	No	No
2233	Placebo	No	No	No	Yes	No	No
2234	Active	No	No	No	Yes	No	No
2235	Placebo	No	No	No	Yes	No	No
2236	Placebo	No	No	No	Yes	No	No

**CONFIDENTIAL**

**Listing 8: Efficacy Assessments**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")

on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Reduced or Stopped Smoking  
(Serbia)**

Subject ID	Group	Reduced smoking by 50% week 12	Stopped week 12	Reduced smoking weeks 9-12	Stopped by 50% week 24	Stopped week 24	Stopped weeks 21-24
2237	Placebo	No	No	No	Yes	No	No
2238	Active	No	No	No	Yes	No	No
2239	Active	No	No	No	Yes	No	No
2240	Active	No	No	No	Yes	No	No
2241	Active	No	No	No	Yes	No	No
2242	Active	Yes	No	No	Yes	No	No
2243	Placebo	No	No	No	Yes	No	No
2244	Placebo	Yes	No	No	Yes	No	No
2245	Active	No	No	No	Yes	Yes	No
2246	Placebo	No	No	No	Yes	No	No
2247	Active	No	No	No	Yes	No	No
2248	Active	No	No	No	Yes	No	No
2249	Placebo	No	No	No	Yes	No	No
2250	Placebo	No	No	No	Yes	No	No
2251	Active	No	No	No	Yes	No	No
2252	Placebo	No	No	No	Yes	No	No
2253	Active	No	No	No	Yes	No	No
2254	Placebo	Yes	No	No	Yes	No	No
2255	Active	No	No	No	No	No	No
2256	Placebo	No	No	No	Yes	No	No
2257	Active	No	Yes	No	Yes	Yes	Yes
2258	Placebo	Yes	No	No	Yes	No	No
2259	Placebo	No	No	No	Yes	No	No
2260	Placebo	No	No	No	Yes	No	No
2261	Active	No	No	No	No	No	No
2262	Active	No	No	No	Yes	Yes	Yes
2263	Placebo	No	No	No	No	No	No
2264	Active	No	No	No	No	No	No
2265	Active	No	No	No	Yes	No	No
2266	Active	No	No	No	Yes	No	No
2267	Active	No	No	No	Yes	No	No
2268	Placebo	No	No	No	No	No	No
2269	Placebo	No	No	No	No	No	No
2270	Placebo	No	No	No	No	Yes	No
2271	Placebo	Yes	No	No	Yes	No	No
2272	Placebo	No	No	No	No	No	No
2273	Active	No	No	No	No	No	No
2274	Placebo	No	No	No	Yes	No	No
2275	Active	Yes	No	No	Yes	Yes	Yes
2276	Active	No	No	No	No	No	No
2277	Active	Yes	No	No	Yes	Yes	Yes
2278	Active	Yes	No	No	No	No	No
2279	Placebo	No	No	No	Yes	No	No
2280	Placebo	Yes	No	No	Yes	No	No
2281	Active	No	No	No	No	No	No
2282	Placebo	Yes	No	No	Yes	No	No
2283	Placebo	No	No	No	No	No	No
2284	Active	No	No	No	No	No	No
2285	Active	No	No	No	No	No	No
2286	Placebo	No	No	No	No	No	No

**CONFIDENTIAL**

**Listing 8: Efficacy Assessments**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")

on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Reduced or Stopped Smoking  
(Serbia)**

Subject ID	Group	Reduced smoking by 50% week 12	Stopped week 12	Reduced smoking weeks 9-12	Stopped by 50% week 24	Stopped week 24	Stopped weeks 21-24
2287	Active	No	No	No	Yes	No	No
2288	Placebo	No	No	No	No	No	No
2289	Active	Yes	No	No	Yes	No	No
2290	Placebo	No	No	No	Yes	No	No
2291	Active	No	No	No	Yes	No	No
2292	Placebo	No	No	No	No	No	No
2293	Placebo	No	No	No	Yes	No	No
2294	Active	No	No	No	No	No	No
2295	Active	Yes	No	No	Yes	Yes	Yes
2296	Active	Yes	Yes	No	Yes	Yes	Yes
2297	Placebo	No	No	No	Yes	No	No
2298	Placebo	No	No	No	Yes	No	No
2299	Active	Yes	No	No	No	No	No
2300	Placebo	No	No	No	Yes	No	No
2301	Active	No	No	No	No	No	No
2302	Placebo	No	No	No	Yes	No	No
2303	Active	No	No	No	No	No	No
2304	Placebo	No	No	No	No	No	No
2305	Placebo	No	No	No	Yes	Yes	No
2306	Active	Yes	No	No	Yes	No	No
3001	Placebo	Yes	No	No	Yes	No	No
3002	Placebo	No	No	No	Yes	No	No
3003	Active	No	No	No	Yes	No	No
3004	Active	Yes	No	No	Yes	No	No
3006	Placebo	No	No	No	Yes	No	No
3007	Active	No	No	No	Yes	No	No
3008	Active	Yes	No	No	Yes	No	No
3009	Placebo	No	No	No	Yes	No	No
3010	Placebo	No	No	No	Yes	No	No
3011	Active	No	No	No	Yes	No	No
3012	Placebo	No	No	No	Yes	No	No
3013	Active	No	No	No	Yes	No	No
3014	Active	No	No	No	Yes	No	No
3015	Active	No	No	No	Yes	No	No
3016	Placebo	No	No	No	Yes	No	No
3017	Placebo	No	No	No	Yes	No	No
3018	Placebo	No	No	No	Yes	No	No
3019	Active	No	No	No	Yes	No	No
3020	Placebo	No	No	No	Yes	No	No
3021	Active	No	No	No	Yes	No	No
3022	Placebo	No	No	No	.	.	.
3023	Active	No	No	No	Yes	No	No
3024	Placebo	No	No	No	Yes	No	No
3025	Placebo	Yes	No	No	Yes	No	No
3026	Placebo	No	No	No	Yes	No	No
3027	Placebo	No	No	No	Yes	No	No
3028	Active	No	No	No	Yes	No	No
3029	Active	No	No	No	Yes	No	No
3030	Active	No	No	No	Yes	No	No
3031	Active	No	No	No	Yes	No	No

**CONFIDENTIAL**

**Listing 8: Efficacy Assessments**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

**Reduced or Stopped Smoking  
(Serbia)**

<b>Subject ID</b>	<b>Group</b>	<b>Reduced smoking by 50% week 12</b>	<b>Stopped week 12</b>	<b>Reduced smoking weeks 9-12</b>	<b>Stopped by 50% week 24</b>	<b>Stopped week 24</b>	<b>Stopped weeks 21-24</b>
3032	Active	No	No	No	Yes	No	No
3033	Placebo	No	No	No	Yes	No	No
3034	Active	No	No	No	Yes	No	No
3035	Placebo	No	No	No	Yes	No	No
3036	Placebo	No	No	No	Yes	No	No
3037	Placebo	No	No	No	Yes	No	No
3038	Active	Yes	No	No	Yes	No	No
3039	Placebo	Yes	No	No	Yes	No	No
3040	Active	No	No	No	Yes	No	No
3041	Placebo	No	No	No	Yes	No	No
3042	Active	No	No	No	Yes	No	No
3043	Placebo	No	No	No	Yes	No	No
3044	Active	No	No	No	Yes	No	No
3045	Active	No	No	No	Yes	No	No
3046	Placebo	No	No	No	Yes	No	No
3047	Active	No	No	No	Yes	No	No
3048	Placebo	No	No	No	Yes	No	No
3049	Placebo	No	No	No	Yes	No	No
3050	Active	No	No	No	Yes	No	No

**CONFIDENTIAL**

**Listing 8: Efficacy Assessments**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")

on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Reduced or Stopped Smoking  
(Serbia)**

Subject ID	Group	Stopped week 36	Stopped weeks 33-36	Stopped weeks 25-36	Stopped weeks 13-36	Stopped week 48	Stopped weeks 45-48	Stopped weeks 37-48	Stopped weeks 25-48
1001	Placebo	.	.	.	.	.	.	.	.
1002	Placebo	No	No	No	No	No	No	No	No
1003	Active	.	.	.	.	.	.	.	.
1004	Active	.	.	.	.	.	.	.	.
1005	Active	No	No	No	No	.	.	.	.
1006	Placebo	.	.	.	.	.	.	.	.
1007	Active	.	.	.	.	.	.	.	.
1008	Active	No	No	No	No	No	No	No	No
1009	Placebo	No	No	No	No	No	No	No	No
1010	Placebo	.	.	.	.	.	.	.	.
1011	Active	.	.	.	.	.	.	.	.
1012	Placebo	.	.	.	.	.	.	.	.
1013	Active	.	.	.	.	.	.	.	.
1014	Active	.	.	.	.	No	No	No	No
1015	Active	.	.	.	.	No	No	No	No
1016	Placebo	No	No	No	No	No	No	No	No
1017	Placebo	.	.	.	.	No	No	No	No
1018	Placebo	.	.	.	.	.	.	.	.
1019	Active	.	.	.	.	.	.	.	.
1020	Placebo	.	.	.	.	No	No	No	No
1021	Active	.	.	.	.	No	No	No	No
1022	Placebo	.	.	.	.	.	.	.	.
1023	Active	No	No	No	No	No	No	No	No
1024	Placebo	.	.	.	.	.	.	.	.
1025	Placebo	.	.	.	.	.	.	.	.
1026	Placebo	.	.	.	.	.	.	.	.
1027	Placebo	.	.	.	.	.	.	.	.
1028	Active	.	.	.	.	.	.	.	.
1029	Active	.	.	.	.	.	.	.	.
1030	Active	No	No	No	No	No	No	No	No
1031	Active	.	.	.	.	.	.	.	.
1032	Active	.	.	.	.	.	.	.	.
1033	Placebo	.	.	.	.	.	.	.	.
1034	Active	.	.	.	.	.	.	.	.
1035	Placebo	.	.	.	.	.	.	.	.
1036	Placebo	.	.	.	.	.	.	.	.
1037	Placebo	No	No	No	No	Yes	No	No	No
1038	Active	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
1039	Placebo	.	.	.	.	.	.	.	.
1040	Active	.	.	.	.	.	.	.	.
1041	Placebo	.	.	.	.	No	No	No	No
1042	Active	.	.	.	.	.	.	.	.
1043	Placebo	.	.	.	.	.	.	.	.
1044	Active	.	.	.	.	No	No	No	No
1045	Active	.	.	.	.	.	.	.	.
1046	Placebo	.	.	.	.	No	No	No	No
1047	Active	.	.	.	.	.	.	.	.
1048	Placebo	.	.	.	.	.	.	.	.
1049	Placebo	.	.	.	.	.	.	.	.
1050	Active	.	.	.	.	.	.	.	.

**CONFIDENTIAL**

**Listing 8: Efficacy Assessments**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Reduced or Stopped Smoking  
(Serbia)**

Subject ID	Group	Stopped week 36	Stopped weeks 33-36	Stopped weeks 25-36	Stopped weeks 13-36	Stopped week 48	Stopped weeks 45-48	Stopped weeks 37-48	Stopped weeks 25-48
1205	Placebo	No	No	No	No	No	No	No	No
1206	Placebo	.	.	.	.	.	.	.	.
1207	Active	.	.	.	.	.	.	.	.
1208	Active	.	.	.	.	.	.	.	.
1209	Active	.	.	.	.	.	.	.	.
1210	Placebo	No	No	No	No	No	No	No	No
1211	Active	.	.	.	.	.	.	.	.
1212	Active	No	No	No	No	No	No	No	No
1213	Placebo	.	.	.	.	.	.	.	.
1214	Placebo	No	No	No	No	.	.	.	.
1215	Active	.	.	.	.	.	.	.	.
1216	Placebo	No	No	No	No	No	No	No	No
1217	Active	.	.	.	.	.	.	.	.
1218	Active	.	.	.	.	.	.	.	.
1219	Active	.	.	.	.	No	No	No	No
1220	Placebo	No	No	No	No	No	No	No	No
1221	Placebo	.	.	.	.	.	.	.	.
1222	Placebo	.	.	.	.	No	No	No	No
1223	Active	.	.	.	.	.	.	.	.
1224	Placebo	.	.	.	.	.	.	.	.
1225	Active	.	.	.	.	No	No	No	No
1226	Placebo	No	No	No	No	No	No	No	No
1227	Active	.	.	.	.	.	.	.	.
1228	Placebo	.	.	.	.	.	.	.	.
1229	Placebo	.	.	.	.	.	.	.	.
1230	Placebo	No	No	No	No	No	No	No	No
1231	Placebo	.	.	.	.	.	.	.	.
1232	Active	.	.	.	.	.	.	.	.
1233	Active	No	No	No	No	No	No	No	No
1234	Active	.	.	.	.	.	.	.	.
1235	Active	No	No	No	No	.	.	.	.
1236	Active	.	.	.	.	.	.	.	.
1237	Placebo	No	No	No	No	No	No	No	No
1238	Active	.	.	.	.	.	.	.	.
1239	Placebo	No	No	No	No	No	No	No	No
1240	Placebo	No	No	No	No	No	No	No	No
1241	Placebo	.	.	.	.	.	.	.	.
1242	Active	No	No	No	No	No	No	No	No
1243	Placebo	No	No	No	No	No	No	No	No
1244	Active	No	No	No	No	No	No	No	No
1245	Placebo	No	No	No	No	No	No	No	No
1246	Active	Yes	Yes	No	No	Yes	Yes	Yes	No
1247	Placebo	No	No	No	No	.	.	.	.
1325	Placebo	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
1326	Placebo	No	No	No	No	No	No	No	No
1327	Active	.	.	.	.	No	No	No	No
1328	Active	Yes	Yes	No	No	Yes	Yes	Yes	No
1329	Active	No	No	No	No	No	No	No	No
1330	Placebo	No	No	No	No	No	No	No	No
1331	Active	No	No	No	No	Yes	Yes	Yes	No

**CONFIDENTIAL**

**Listing 8: Efficacy Assessments**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

**Reduced or Stopped Smoking  
(Serbia)**

Subject ID	Group	Stopped week 36	Stopped weeks 33-36	Stopped weeks 25-36	Stopped weeks 13-36	Stopped week 48	Stopped weeks 45-48	Stopped weeks 37-48	Stopped weeks 25-48
1332	Active	No	No	No	No	No	No	No	No
1333	Placebo	No	No	No	No	No	No	No	No
1334	Placebo	No	No	No	No	No	No	No	No
1335	Active	No	No	No	No	No	No	No	No
1336	Placebo	No	No	No	No	No	No	No	No
1337	Active	No	No	No	No	No	No	No	No
1338	Active	No	No	No	No	Yes	Yes	No	No
1339	Active	No	No	No	No	No	No	No	No
1340	Placebo	No	No	No	No	No	No	No	No
1341	Placebo	No	No	No	No	No	No	No	No
1342	Placebo	.	.	.	.	.	.	.	.
1343	Active	No	No	No	No	Yes	Yes	Yes	No
1344	Placebo	No	No	No	No	Yes	Yes	No	No
1345	Active	Yes	Yes	No	No	Yes	Yes	Yes	No
1346	Placebo	No	No	No	No	No	No	No	No
1347	Active	.	.	.	.	.	.	.	.
1348	Placebo	.	.	.	.	.	.	.	.
1349	Placebo	.	.	.	.	.	.	.	.
2001	Placebo	No	No	No	No	No	No	No	No
2002	Placebo	No	No	No	No	No	No	No	No
2003	Active	No	No	No	No	No	No	No	No
2004	Active	.	.	.	.	.	.	.	.
2005	Active	.	.	.	.	.	.	.	.
2006	Placebo	.	.	.	.	.	.	.	.
2007	Active	.	.	.	.	.	.	.	.
2008	Active	.	.	.	.	.	.	.	.
2009	Placebo	.	.	.	.	.	.	.	.
2010	Placebo	No	No	No	No	No	No	No	No
2011	Active	.	.	.	.	.	.	.	.
2012	Placebo	.	.	.	.	.	.	.	.
2013	Active	.	.	.	.	.	.	.	.
2014	Active	.	.	.	.	.	.	.	.
2015	Active	.	.	.	.	.	.	.	.
2016	Placebo	No	No	No	No	Yes	Yes	No	No
2017	Placebo	.	.	.	.	.	.	.	.
2018	Placebo	.	.	.	.	.	.	.	.
2019	Active	.	.	.	.	.	.	.	.
2020	Placebo	.	.	.	.	.	.	.	.
2021	Active	No	No	No	No	No	No	No	No
2022	Placebo	No	No	No	No	No	No	No	No
2023	Active	.	.	.	.	.	.	.	.
2024	Placebo	.	.	.	.	.	.	.	.
2025	Placebo	No	No	No	No	No	No	No	No
2026	Placebo	No	No	No	No	Yes	Yes	No	No
2027	Placebo	No	No	No	No	No	No	No	No
2028	Active	Yes	No	No	No	Yes	Yes	No	No
2029	Active	No	No	No	No	No	No	No	No
2030	Active	No	No	No	No	No	No	No	No
2031	Active	No	No	No	No	.	.	.	.
2032	Active	No	No	No	No	No	No	No	No

**CONFIDENTIAL**

**Listing 8: Efficacy Assessments**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")

on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Reduced or Stopped Smoking  
(Serbia)**

Subject ID	Group	Stopped week 36	Stopped weeks 33-36	Stopped weeks 25-36	Stopped weeks 13-36	Stopped week 48	Stopped weeks 45-48	Stopped weeks 37-48	Stopped weeks 25-48
2033	Placebo	No	No	No	No	No	No	No	No
2034	Active	.	.	.	.	.	.	.	.
2035	Placebo	No	No	No	No	No	No	No	No
2036	Placebo	No	No	No	No	No	No	No	No
2037	Placebo	.	.	.	.	.	.	.	.
2038	Active	.	.	.	.	.	.	.	.
2039	Placebo	No	No	No	No	No	No	No	No
2040	Active	.	.	.	.	.	.	.	.
2041	Placebo	.	.	.	.	No	No	No	No
2042	Active	No	No	No	No	No	No	No	No
2043	Placebo	.	.	.	.	.	.	.	.
2044	Active	No	No	No	No	No	No	No	No
2045	Active	No	No	No	No	No	No	No	No
2046	Placebo	.	.	.	.	.	.	.	.
2047	Active	Yes	No	No	No	Yes	Yes	No	No
2048	Placebo	Yes	Yes	No	No	Yes	Yes	Yes	No
2049	Placebo	No	No	No	No	No	No	No	No
2050	Active	No	No	No	No	No	No	No	No
2205	Active	No	No	No	No	No	No	No	No
2206	Placebo	No	No	No	No	No	No	No	No
2207	Placebo	No	No	No	No	No	No	No	No
2208	Active	No	No	No	No	No	No	No	No
2209	Active	No	No	No	No	No	No	No	No
2210	Placebo	Yes	Yes	No	No	Yes	Yes	Yes	No
2211	Placebo	No	No	No	No	No	No	No	No
2212	Placebo	No	No	No	No	No	No	No	No
2213	Active	No	No	No	No	No	No	No	No
2214	Active	No	No	No	No	No	No	No	No
2215	Active	No	No	No	No	No	No	No	No
2216	Placebo	No	No	No	No	No	No	No	No
2217	Active	No	No	No	No	Yes	Yes	No	No
2218	Placebo	No	No	No	No	No	No	No	No
2219	Active	No	No	No	No	No	No	No	No
2220	Placebo	No	No	No	No	No	No	No	No
2221	Placebo	No	No	No	No	Yes	Yes	No	No
2222	Active	No	No	No	No	No	No	No	No
2223	Placebo	No	No	No	No	No	No	No	No
2224	Placebo	No	No	No	No	No	No	No	No
2225	Placebo	No	No	No	No	No	No	No	No
2226	Active	No	No	No	No	No	No	No	No
2227	Active	No	No	No	No	No	No	No	No
2228	Active	No	No	No	No	No	No	No	No
2229	Placebo	No	No	No	No	No	No	No	No
2230	Active	No	No	No	No	No	No	No	No
2231	Active	No	No	No	No	No	No	No	No
2232	Placebo	No	No	No	No	No	No	No	No
2233	Placebo	No	No	No	No	No	No	No	No
2234	Active	No	No	No	No	No	No	No	No
2235	Placebo	No	No	No	No	No	No	No	No
2236	Placebo	No	No	No	No	Yes	No	No	No

**CONFIDENTIAL**

**Listing 8: Efficacy Assessments**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")

on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Reduced or Stopped Smoking  
(Serbia)**

Subject ID	Group	Stopped week 36	Stopped weeks 33-36	Stopped weeks 25-36	Stopped weeks 13-36	Stopped week 48	Stopped weeks 45-48	Stopped weeks 37-48	Stopped weeks 25-48
2237	Placebo	No	No	No	No	No	No	No	No
2238	Active	No	No	No	No	Yes	No	No	No
2239	Active	No	No	No	No	No	No	No	No
2240	Active	No	No	No	No	No	No	No	No
2241	Active	No	No	No	No	No	No	No	No
2242	Active	Yes	Yes	No	No	Yes	Yes	Yes	No
2243	Placebo	No	No	No	No	No	No	No	No
2244	Placebo	No	No	No	No	No	No	No	No
2245	Active	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
2246	Placebo	No	No	No	No	No	No	No	No
2247	Active	No	No	No	No	No	No	No	No
2248	Active	No	No	No	No	No	No	No	No
2249	Placebo	No	No	No	No	No	No	No	No
2250	Placebo	No	No	No	No	Yes	No	No	No
2251	Active	No	No	No	No	No	No	No	No
2252	Placebo	No	No	No	No	No	No	No	No
2253	Active	No	No	No	No	No	No	No	No
2254	Placebo	No	No	No	No	No	No	No	No
2255	Active	.	.	.	.	.	.	.	.
2256	Placebo	No	No	No	No	Yes	Yes	No	No
2257	Active	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2258	Placebo	No	No	No	No	Yes	Yes	No	No
2259	Placebo	Yes	Yes	No	No	Yes	Yes	Yes	No
2260	Placebo	No	No	No	No	No	No	No	No
2261	Active	.	.	.	.	.	.	.	.
2262	Active	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
2263	Placebo	.	.	.	.	.	.	.	.
2264	Active	.	.	.	.	.	.	.	.
2265	Active	No	No	No	No	No	No	No	No
2266	Active	No	No	No	No	No	No	No	No
2267	Active	No	No	No	No	No	No	No	No
2268	Placebo	.	.	.	.	.	.	.	.
2269	Placebo	.	.	.	.	.	.	.	.
2270	Placebo	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
2271	Placebo	No	No	No	No	No	No	No	No
2272	Placebo	.	.	.	.	.	.	.	.
2273	Active	.	.	.	.	.	.	.	.
2274	Placebo	No	No	No	No	No	No	No	No
2275	Active	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
2276	Active	.	.	.	.	.	.	.	.
2277	Active	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2278	Active	.	.	.	.	.	.	.	.
2279	Placebo	No	No	No	No	No	No	No	No
2280	Placebo	No	No	No	No	No	No	No	No
2281	Active	.	.	.	.	.	.	.	.
2282	Placebo	No	No	No	No	No	No	No	No
2283	Placebo	.	.	.	.	.	.	.	.
2284	Active	.	.	.	.	.	.	.	.
2285	Active	.	.	.	.	.	.	.	.
2286	Placebo	.	.	.	.	.	.	.	.

**CONFIDENTIAL**

**Listing 8: Efficacy Assessments**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")

on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Reduced or Stopped Smoking  
(Serbia)**

Subject ID	Group	Stopped week 36	Stopped weeks 33-36	Stopped weeks 25-36	Stopped weeks 13-36	Stopped week 48	Stopped weeks 45-48	Stopped weeks 37-48	Stopped weeks 25-48
2287	Active	No	No	No	No	.	.	.	.
2288	Placebo	.	.	.	.	.	.	.	.
2289	Active	No	No	No	No	.	.	.	.
2290	Placebo	No	No	No	No	.	.	.	.
2291	Active	No	No	No	No	.	.	.	.
2292	Placebo	.	.	.	.	.	.	.	.
2293	Placebo	No	No	No	No	.	.	.	.
2294	Active	.	.	.	.	.	.	.	.
2295	Active	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
2296	Active	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
2297	Placebo	No	No	No	No	.	.	.	.
2298	Placebo	No	No	No	No	.	.	.	.
2299	Active	.	.	.	.	.	.	.	.
2300	Placebo	No	No	No	No	No	No	No	No
2301	Active	.	.	.	.	.	.	.	.
2302	Placebo	No	No	No	No	No	No	No	No
2303	Active	.	.	.	.	.	.	.	.
2304	Placebo	.	.	.	.	.	.	.	.
2305	Placebo	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
2306	Active	No	No	No	No	.	.	.	.
3001	Placebo	No	No	No	No	No	No	No	No
3002	Placebo	No	No	No	No	No	No	No	No
3003	Active	No	No	No	No	No	No	No	No
3004	Active	No	No	No	No	Yes	No	No	No
3006	Placebo	No	No	No	No	No	No	No	No
3007	Active	No	No	No	No	Yes	Yes	No	No
3008	Active	No	No	No	No	No	No	No	No
3009	Placebo	No	No	No	No	No	No	No	No
3010	Placebo	No	No	No	No	No	No	No	No
3011	Active	No	No	No	No	Yes	Yes	No	No
3012	Placebo	No	No	No	No	No	No	No	No
3013	Active	No	No	No	No	Yes	Yes	No	No
3014	Active	No	No	No	No	No	No	No	No
3015	Active	No	No	No	No	No	No	No	No
3016	Placebo	No	No	No	No	No	No	No	No
3017	Placebo	No	No	No	No	No	No	No	No
3018	Placebo	No	No	No	No	No	No	No	No
3019	Active	No	No	No	No	No	No	No	No
3020	Placebo	No	No	No	No	No	No	No	No
3021	Active	No	No	No	No	No	No	No	No
3022	Placebo	.	.	.	.	.	.	.	.
3023	Active	No	No	No	No	No	No	No	No
3024	Placebo	No	No	No	No	No	No	No	No
3025	Placebo	No	No	No	No	No	No	No	No
3026	Placebo	No	No	No	No	No	No	No	No
3027	Placebo	No	No	No	No	No	No	No	No
3028	Active	No	No	No	No	No	No	No	No
3029	Active	No	No	No	No	No	No	No	No
3030	Active	No	No	No	No	No	No	No	No
3031	Active	No	No	No	No	No	No	No	No

**CONFIDENTIAL**

**Listing 8: Efficacy Assessments**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**Reduced or Stopped Smoking  
(Serbia)**

Subject ID	Group	Stopped week 36	Stopped weeks 33-36	Stopped weeks 25-36	Stopped weeks 13-36	Stopped week 48	Stopped weeks 45-48	Stopped weeks 37-48	Stopped weeks 25-48
3032	Active	No	No	No	No	No	No	No	No
3033	Placebo	No	No	No	No	No	No	No	No
3034	Active	No	No	No	No	No	No	No	No
3035	Placebo	No	No	No	No	No	No	No	No
3036	Placebo	No	No	No	No	No	No	No	No
3037	Placebo	No	No	No	No	No	No	No	No
3038	Active	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes
3039	Placebo	No	No	No	No	No	No	No	No
3040	Active	No	No	No	No	No	No	No	No
3041	Placebo	No	No	No	No	No	No	No	No
3042	Active	No	No	No	No	No	No	No	No
3043	Placebo	No	No	No	No	No	No	No	No
3044	Active	No	No	No	No	No	No	No	No
3045	Active	No	No	No	No	No	No	No	No
3046	Placebo	No	No	No	No	No	No	No	No
3047	Active	No	No	No	No	No	No	No	No
3048	Placebo	No	No	No	No	No	No	No	No
3049	Placebo	No	No	No	No	No	No	No	No
3050	Active	No	No	No	No	Yes	No	No	No

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**Listing 9: Dates of Treatments and Completion/Withdrawal**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

**(Serbia)**

<b>Subject ID</b>	<b>Group</b>	<b>Start date of treatment</b>	<b>End date of treatment</b>	<b>End Week on Study</b>	<b>Completed Study?</b>	<b>Primary Reason for Discontinuation</b>
1001	Placebo	20080128	20081223	48	No	Failure to achieve smoking reduction at Week 24
1002	Placebo	20080128	20090113	51	Yes	
1003	Active	20080128	20081006	37	No	Withdrawal of Consent
1004	Active	20080130	20080704	23	No	Protocol Violation
1005	Active	20080130	20081231	49	No	Withdrawal of Consent
1006	Placebo	20080130	20080716	25	No	Failure to achieve smoking reduction at Week 24
1007	Active	20080204	20080321	7	No	Adverse Event (Adverse Reaction)
1008	Active	20080204	20090115	50	Yes	
1009	Placebo	20080206	20090109	49	Yes	
1010	Placebo	20080207	20080729	25	No	Failure to achieve smoking reduction at Week 24
1011	Active	20080207	20081016	37	No	Failure to achieve smoking reduction at Week 24
1012	Placebo	20080207	20080731	26	No	Failure to achieve smoking reduction at Week 24
1013	Active	20080208	20080925	33	No	Failure to achieve smoking reduction at Week 24
1014	Active	20080209	20080906	31	No	Withdrawal of Consent
1015	Active	20080209	20080619	19	No	Protocol Violation
1016	Placebo	20080209	20090109	48	Yes	
1017	Placebo	20080209	20080906	31	No	Withdrawal of Consent
1018	Placebo	20080211	20080415	10	No	Withdrawal of Consent
1019	Active	20080213	20080910	31	No	Failure to achieve smoking reduction at Week 24
1020	Placebo	20080213	20080814	27	No	Protocol Violation
1021	Active	20080214	20080908	30	No	Lost to Follow Up
1022	Placebo	20080214	20080331	7	No	Withdrawal of Consent
1023	Active	20080218	20090120	49	Yes	
1024	Placebo	20080219	20080623	18	No	Protocol Violation
1025	Placebo	20080219	20080923	32	No	Failure to achieve smoking reduction at Week 24
1026	Placebo	20080219	20080519	13	No	Withdrawal of Consent
1027	Placebo	20080220	20080918	31	No	Failure to achieve smoking reduction at Week 24
1028	Active	20080220	20080923	31	No	Failure to achieve smoking reduction at Week 24
1029	Active	20080221	20080903	28	No	Lost to Follow Up
1030	Active	20080221	20090128	49	Yes	
1031	Active	20080221	20080923	31	No	Failure to achieve smoking reduction at Week 24
1032	Active	20080222	20080404	7	No	Withdrawal of Consent
1033	Placebo	20080222	20080922	31	No	Failure to achieve smoking reduction at Week 24
1034	Active	20080222	20080514	12	No	Lost to Follow Up
1035	Placebo	20080225	20080731	23	No	Failure to achieve smoking reduction at Week 24
1036	Placebo	20080225	20080512	12	No	Protocol Violation
1037	Placebo	20080226	20090126	48	Yes	
1038	Active	20080226	20090213	51	Yes	

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**Listing 9: Dates of Treatments and Completion/Withdrawal**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

(Serbia)

Subject ID	Group	Start date of treatment	End date of treatment	End Week on Study	Completed Study?	Primary Reason for Discontinuation
1039	Placebo	20080226	20080522	13	No	Protocol Violation
1040	Active	20080226	20080522	13	No	Withdrawal of Consent
1041	Placebo	20080227	20080910	29	No	Withdrawal of Consent
1042	Active	20080227	20080703	19	No	Withdrawal of Consent
1043	Placebo	20080227	20081120	39	No	Failure to achieve smoking reduction at Week 24
1044	Active	20080229	20080523	13	No	Withdrawal of Consent
1045	Active	20080229	20080314	3	No	Adverse Event (Adverse Reaction)
1046	Placebo	20080229	20080913	29	No	Protocol Violation
1047	Active	20080303	20080701	18	No	Withdrawal of Consent
1048	Placebo	20080303	20080701	18	No	Withdrawal of Consent
1049	Placebo	20080306	20080630	17	No	Withdrawal of Consent
1050	Active	20080311	20080718	19	No	Lost to Follow Up
1205	Placebo	20080509	20090414	49	Yes	.
1206	Placebo	20080509	20080805	13	No	Withdrawal of Consent
1207	Active	20080512	20080801	12	No	Withdrawal of Consent
1208	Active	20080513	20080917	19	No	Withdrawal of Consent
1209	Active	20080513	20080820	15	No	Withdrawal of Consent
1210	Placebo	20080513	20090409	48	Yes	.
1211	Active	20080513	20080830	16	No	Withdrawal of Consent
1212	Active	20080515	20090423	50	Yes	.
1213	Placebo	20080521	20081215	30	No	Lost to Follow Up
1214	Placebo	20080523	20090430	49	No	Lost to Follow Up
1215	Active	20080523	20081105	24	No	Failure to achieve smoking reduction at Week 24
1216	Placebo	20080526	20090429	49	Yes	.
1217	Active	20080526	20081118	26	No	Lost to Follow Up
1218	Active	20080527	20080820	13	No	Withdrawal of Consent
1219	Active	20080602	20080904	14	No	Withdrawal of Consent
1220	Placebo	20080603	20090504	48	Yes	.
1221	Placebo	20080604	20081119	25	No	Withdrawal of Consent
1222	Placebo	20080604	20090326	43	No	Lost to Follow Up
1223	Active	20080605	20090212	37	No	Protocol Violation
1224	Placebo	20080605	20090217	37	No	Other
1225	Active	20080605	20081015	19	No	Withdrawal of Consent
1226	Placebo	20080606	20090505	48	Yes	.
1227	Active	20080607	20081218	28	No	Lost to Follow Up
1228	Placebo	20080607	20081229	30	No	Withdrawal of Consent
1229	Placebo	20080607	20090217	37	No	Lost to Follow Up
1230	Placebo	20080821	20090724	49	Yes	.
1231	Placebo	20090203	20090728	26	No	Failure to achieve smoking reduction at Week 24
1232	Active	20090204	20090421	11	No	Withdrawal of Consent
1233	Active	20090205	20100115	50	Yes	.
1234	Active	20090206	20090508	14	No	Withdrawal of Consent
1235	Active	20090210	20100115	49	No	Withdrawal of Consent
1236	Active	20090211	20090508	13	No	Withdrawal of Consent
1237	Placebo	20090214	20100123	50	Yes	.
1238	Active	20090214	20090911	30	No	Withdrawal of Consent
1239	Placebo	20090214	20100123	50	Yes	.
1240	Placebo	20090214	20100123	50	Yes	.

**CONFIDENTIAL**

**Listing 9: Dates of Treatments and Completion/Withdrawal**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials

(Serbia)

<b>Subject ID</b>	<b>Group</b>	<b>Start date of treatment</b>	<b>End date of treatment</b>	<b>End Week on Study</b>	<b>Completed Study?</b>	<b>Primary Reason for Discontinuation</b>
1241	Placebo	20090214	20090509	13	No	Lost to Follow Up
1242	Active	20090214	20100123	50	Yes	.
1243	Placebo	20090214	20100123	50	Yes	.
1244	Active	20090214	20100123	50	Yes	.
1245	Placebo	20090214	20100123	50	Yes	.
1246	Active	20090214	20100123	50	Yes	.
1247	Placebo	20090223	20100122	48	No	Lost to Follow Up
1325	Placebo	20090406	20100315	50	Yes	.
1326	Placebo	20090420	20100324	49	Yes	.
1327	Active	20090420	20091228	37	No	Withdrawal of Consent
1328	Active	20090420	20100322	49	Yes	.
1329	Active	20090420	20100324	49	Yes	.
1330	Placebo	20090420	20100326	49	Yes	.
1331	Active	20090420	20100315	48	Yes	.
1332	Active	20090420	20100324	49	Yes	.
1333	Placebo	20090420	20100324	49	Yes	.
1334	Placebo	20090420	20100322	49	Yes	.
1335	Active	20090420	20100322	49	Yes	.
1336	Placebo	20090420	20100324	49	Yes	.
1337	Active	20090422	20100325	49	Yes	.
1338	Active	20090424	20100322	48	Yes	.
1339	Active	20090424	20100324	48	Yes	.
1340	Placebo	20090424	20100322	48	Yes	.
1341	Placebo	20090428	20100324	48	Yes	.
1342	Placebo	20090501	20091014	24	No	Failure to achieve smoking reduction at Week 24
1343	Active	20090501	20100326	48	Yes	.
1344	Placebo	20090501	20100326	48	Yes	.
1345	Active	20090501	20100326	48	Yes	.
1346	Placebo	20090501	20100326	48	Yes	.
1347	Active	20090429	20091023	26	No	Failure to achieve smoking reduction at Week 24
1348	Placebo	20090429	20091023	26	No	Failure to achieve smoking reduction at Week 24
1349	Placebo	20090429	20100106	37	No	Lost to Follow Up
2001	Placebo	20080211	20090112	49	Yes	.
2002	Placebo	20080211	20090108	48	Yes	.
2003	Active	20080218	20090121	49	Yes	.
2004	Active	20080218	20080811	26	No	Failure to achieve smoking reduction at Week 24
2005	Active	20080218	20080811	26	No	Failure to achieve smoking reduction at Week 24
2006	Placebo	20080218	20080811	26	No	Failure to achieve smoking reduction at Week 24
2007	Active	20080219	20080811	25	No	Failure to achieve smoking reduction at Week 24
2008	Active	20080219	20080811	25	No	Failure to achieve smoking reduction at Week 24
2009	Placebo	20080220	20080813	26	No	Failure to achieve smoking reduction at Week 24
2010	Placebo	20080220	20090120	48	Yes	.

**CONFIDENTIAL**

**Listing 9: Dates of Treatments and Completion/Withdrawal**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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**(Serbia)**

<b>Subject ID</b>	<b>Group</b>	<b>Start date of treatment</b>	<b>End date of treatment</b>	<b>End Week on Study</b>	<b>Completed Study?</b>	<b>Primary Reason for Discontinuation</b>
2011	Active	20080220	20080813	26	No	Failure to achieve smoking reduction at Week 24
2012	Placebo	20080220	20080813	26	No	Failure to achieve smoking reduction at Week 24
2013	Active	20080221	20080811	25	No	Withdrawal of Consent
2014	Active	20080221	20080811	25	No	Failure to achieve smoking reduction at Week 24
2015	Active	20080221	20080811	25	No	Failure to achieve smoking reduction at Week 24
2016	Placebo	20080221	20090128	49	Yes	.
2017	Placebo	20080221	20080808	25	No	Failure to achieve smoking reduction at Week 24
2018	Placebo	20080221	20080813	25	No	Failure to achieve smoking reduction at Week 24
2019	Active	20080221	20080813	25	No	Withdrawal of Consent
2020	Placebo	20080305	20080820	25	No	Failure to achieve smoking reduction at Week 24
2021	Active	20080305	20090206	49	Yes	.
2022	Placebo	20080305	20090206	49	Yes	.
2023	Active	20080305	20080826	25	No	Failure to achieve smoking reduction at Week 24
2024	Placebo	20080306	20081015	32	No	Withdrawal of Consent
2025	Placebo	20080317	20090223	50	Yes	.
2026	Placebo	20080317	20090220	49	Yes	.
2027	Placebo	20080317	20090217	49	Yes	.
2028	Active	20080318	20090216	48	Yes	.
2029	Active	20080318	20090216	48	Yes	.
2030	Active	20080318	20090220	49	Yes	.
2031	Active	20080320	20081201	37	No	Withdrawal of Consent
2032	Active	20080325	20090302	49	Yes	.
2033	Placebo	20080325	20090302	49	Yes	.
2034	Active	20080325	20080904	24	No	Withdrawal of Consent
2035	Placebo	20080325	20090302	49	Yes	.
2036	Placebo	20080325	20090225	49	Yes	.
2037	Placebo	20080401	20080805	19	No	Withdrawal of Consent
2038	Active	20080401	20080805	19	No	Withdrawal of Consent
2039	Placebo	20080403	20090312	50	Yes	.
2040	Active	20080403	20080923	25	No	Failure to achieve smoking reduction at Week 24
2041	Placebo	20080403	20080925	26	No	Withdrawal of Consent
2042	Active	20080404	20090304	48	Yes	.
2043	Placebo	20080408	20080707	13	No	Withdrawal of Consent
2044	Active	20080410	20090319	50	Yes	.
2045	Active	20080410	20090316	49	Yes	.
2046	Placebo	20080410	20081001	25	No	Failure to achieve smoking reduction at Week 24
2047	Active	20080410	20090319	50	Yes	.
2048	Placebo	20080415	20090319	49	Yes	.
2049	Placebo	20080418	20090319	48	Yes	.
2050	Active	20080424	20090323	48	Yes	.
2205	Active	20080918	20090823	49	Yes	.

**CONFIDENTIAL**

**Listing 9: Dates of Treatments and Completion/Withdrawal**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

(Serbia)

Subject ID	Group	Start date of treatment	End date of treatment	End Week on Study	Completed Study?	Primary Reason for Discontinuation
2206	Placebo	20080918	20090823	49	Yes	.
2207	Placebo	20080923	20090821	48	Yes	.
2208	Active	20080925	20090819	47	Yes	.
2209	Active	20080926	20090821	48	Yes	.
2210	Placebo	20080926	20090821	48	Yes	.
2211	Placebo	20080926	20090821	48	Yes	.
2212	Placebo	20080929	20090904	49	Yes	.
2213	Active	20081002	20090904	49	Yes	.
2214	Active	20081003	20090904	49	Yes	.
2215	Active	20081020	20090921	49	Yes	.
2216	Placebo	20081020	20090921	49	Yes	.
2217	Active	20081020	20090922	49	Yes	.
2218	Placebo	20081022	20090921	48	Yes	.
2219	Active	20081023	20090921	48	Yes	.
2220	Placebo	20081028	20090928	48	Yes	.
2221	Placebo	20081103	20091004	48	Yes	.
2222	Active	20081103	20091004	48	Yes	.
2223	Placebo	20081103	20091006	49	Yes	.
2224	Placebo	20081103	20091009	49	Yes	.
2225	Placebo	20081104	20091005	48	Yes	.
2226	Active	20081105	20091014	50	Yes	.
2227	Active	20081105	20091014	50	Yes	.
2228	Active	20081105	20091014	50	Yes	.
2229	Placebo	20081105	20091014	50	Yes	.
2230	Active	20081107	20091015	49	Yes	.
2231	Active	20081110	20091017	49	Yes	.
2232	Placebo	20081110	20091017	49	Yes	.
2233	Placebo	20081110	20091017	49	Yes	.
2234	Active	20081110	20091018	49	Yes	.
2235	Placebo	20081121	20091028	49	Yes	.
2236	Placebo	20081124	20091102	50	Yes	.
2237	Placebo	20081124	20091102	50	Yes	.
2238	Active	20081128	20091102	49	Yes	.
2239	Active	20081204	20091105	49	Yes	.
2240	Active	20081204	20091105	49	Yes	.
2241	Active	20081204	20091105	49	Yes	.
2242	Active	20081204	20091105	49	Yes	.
2243	Placebo	20081204	20091105	49	Yes	.
2244	Placebo	20081204	20091105	49	Yes	.
2245	Active	20081204	20091105	49	Yes	.
2246	Placebo	20081209	20091030	47	Yes	.
2247	Active	20081209	20091106	48	Yes	.
2248	Active	20081212	20091118	49	Yes	.
2249	Placebo	20081215	20091120	49	Yes	.
2250	Placebo	20081216	20091118	49	Yes	.
2251	Active	20081216	20091118	49	Yes	.
2252	Placebo	20081216	20091118	49	Yes	.
2253	Active	20081216	20091118	49	Yes	.
2254	Placebo	20081216	20091118	49	Yes	.
2255	Active	20081223	20090608	24	No	Failure to achieve smoking reduction at Week 24

**CONFIDENTIAL**

**Listing 9: Dates of Treatments and Completion/Withdrawal**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

**(Serbia)**

<b>Subject ID</b>	<b>Group</b>	<b>Start date of treatment</b>	<b>End date of treatment</b>	<b>End Week on Study</b>	<b>Completed Study?</b>	<b>Primary Reason for Discontinuation</b>
2256	Placebo	20081225	20091130	49	Yes	.
2257	Active	20081227	20091207	50	Yes	.
2258	Placebo	20081226	20091130	49	Yes	.
2259	Placebo	20081226	20091130	49	Yes	.
2260	Placebo	20081230	20091207	49	Yes	.
2261	Active	20090112	20090629	25	No	Failure to achieve smoking reduction at Week 24
2262	Active	20090112	20091208	48	Yes	.
2263	Placebo	20090121	20090708	25	No	Failure to achieve smoking reduction at Week 24
2264	Active	20090121	20090708	25	No	Failure to achieve smoking reduction at Week 24
2265	Active	20090122	20091223	48	Yes	.
2266	Active	20090122	20091223	48	Yes	.
2267	Active	20090122	20091228	49	Yes	.
2268	Placebo	20090127	20090717	25	No	Failure to achieve smoking reduction at Week 24
2269	Placebo	20090128	20090713	24	No	Failure to achieve smoking reduction at Week 24
2270	Placebo	20090130	20091229	48	Yes	.
2271	Placebo	20090130	20091228	48	Yes	.
2272	Placebo	20090204	20090720	24	No	Failure to achieve smoking reduction at Week 24
2273	Active	20090204	20090722	25	No	Failure to achieve smoking reduction at Week 24
2274	Placebo	20090204	20091228	47	Yes	.
2275	Active	20090204	20091229	47	Yes	.
2276	Active	20090204	20090722	25	No	Failure to achieve smoking reduction at Week 24
2277	Active	20090204	20091229	47	Yes	.
2278	Active	20090204	20090721	24	No	Failure to achieve smoking reduction at Week 24
2279	Placebo	20090204	20091228	47	Yes	.
2280	Placebo	20090204	20091228	47	Yes	.
2281	Active	20090204	20090721	24	No	Failure to achieve smoking reduction at Week 24
2282	Placebo	20090204	20091229	47	Yes	.
2283	Placebo	20090204	20090722	25	No	Failure to achieve smoking reduction at Week 24
2284	Active	20090204	20090722	25	No	Failure to achieve smoking reduction at Week 24
2285	Active	20090204	20090721	24	No	Failure to achieve smoking reduction at Week 24
2286	Placebo	20090204	20090721	24	No	Failure to achieve smoking reduction at Week 24
2287	Active	20090225	20100205	50	No	Lost to Follow Up
2288	Placebo	20090305	20090824	25	No	Failure to achieve smoking reduction at Week 24
2289	Active	20090305	20100120	46	No	Lost to Follow Up
2290	Placebo	20090305	20100215	50	No	Lost to Follow Up
2291	Active	20090305	20100330	56	No	Lost to Follow Up

**CONFIDENTIAL**

**Listing 9: Dates of Treatments and Completion/Withdrawal**  
Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

(Serbia)

Subject ID	Group	Start date of treatment	End date of treatment	End Week on Study	Completed Study?	Primary Reason for Discontinuation
2292	Placebo	20090305	20090825	25	No	Failure to achieve smoking reduction at Week 24
2293	Placebo	20090323	20100330	54	No	Lost to Follow Up
2294	Active	20090323	20090914	26	No	Failure to achieve smoking reduction at Week 24
2295	Active	20090323	20100227	49	Yes	.
2296	Active	20090323	20100227	49	Yes	.
2297	Placebo	20090323	20100305	50	No	Lost to Follow Up
2298	Placebo	20090323	20100305	50	No	Lost to Follow Up
2299	Active	20090324	20090908	25	No	Failure to achieve smoking reduction at Week 24
2300	Placebo	20090324	20100304	50	Yes	.
2301	Active	20090327	20090908	24	No	Failure to achieve smoking reduction at Week 24
2302	Placebo	20090327	20100306	50	Yes	.
2303	Active	20090327	20090908	24	No	Failure to achieve smoking reduction at Week 24
2304	Placebo	20090327	20090915	25	No	Failure to achieve smoking reduction at Week 24
2305	Placebo	20090327	20100304	49	Yes	.
2306	Active	20090406	20100330	52	No	Lost to Follow Up
3001	Placebo	20080507	20090414	49	Yes	.
3002	Placebo	20080507	20090414	49	Yes	.
3003	Active	20080516	20090422	49	Yes	.
3004	Active	20080526	20090427	49	Yes	.
3006	Placebo	20080602	20090508	49	Yes	.
3007	Active	20080605	20090511	49	Yes	.
3008	Active	20080605	20090511	49	Yes	.
3009	Placebo	20080605	20090511	49	Yes	.
3010	Placebo	20080606	20090511	49	Yes	.
3011	Active	20080623	20090525	49	Yes	.
3012	Placebo	20080623	20090525	49	Yes	.
3013	Active	20080624	20090526	49	Yes	.
3014	Active	20080625	20090525	48	Yes	.
3015	Active	20080626	20090525	48	Yes	.
3016	Placebo	20080630	20090528	48	Yes	.
3017	Placebo	20080701	20090527	48	Yes	.
3018	Placebo	20080701	20090528	48	Yes	.
3019	Active	20080701	20090528	48	Yes	.
3020	Placebo	20080702	20090527	48	Yes	.
3021	Active	20080703	20090609	49	Yes	.
3022	Placebo	20080704	20091119	72	No	Withdrawal of Consent
3023	Active	20080716	20090617	49	Yes	.
3024	Placebo	20080716	20090617	49	Yes	.
3025	Placebo	20080731	20090630	48	Yes	.
3026	Placebo	20080731	20090630	48	Yes	.
3027	Placebo	20080731	20090630	48	Yes	.
3028	Active	20080731	20090630	48	Yes	.
3029	Active	20080731	20090630	48	Yes	.
3030	Active	20080805	20090704	48	Yes	.
3031	Active	20080805	20090702	48	Yes	.

**CONFIDENTIAL**

**Listing 9: Dates of Treatments and Completion/Withdrawal**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

(Serbia)

<b>Subject ID</b>	<b>Group</b>	<b>Start date of treatment</b>	<b>End date of treatment</b>	<b>End Week on Study</b>	<b>Completed Study?</b>	<b>Primary Reason for Discontinuation</b>
3032	Active	20080806	20090704	48	Yes	.
3033	Placebo	20080808	20090712	49	Yes	.
3034	Active	20080808	20090714	49	Yes	.
3035	Placebo	20080812	20090713	48	Yes	.
3036	Placebo	20080812	20090713	48	Yes	.
3037	Placebo	20080812	20090713	48	Yes	.
3038	Active	20080822	20090727	49	Yes	.
3039	Placebo	20080901	20090805	49	Yes	.
3040	Active	20080902	20090728	48	Yes	.
3041	Placebo	20080909	20090810	48	Yes	.
3042	Active	20080909	20090810	48	Yes	.
3043	Placebo	20080909	20090812	49	Yes	.
3044	Active	20080909	20090811	49	Yes	.
3045	Active	20080910	20090811	48	Yes	.
3046	Placebo	20080915	20090813	48	Yes	.
3047	Active	20080915	20090814	48	Yes	.
3048	Placebo	20080915	20090819	49	Yes	.
3049	Placebo	20080917	20090814	48	Yes	.
3050	Active	20080917	20090814	48	Yes	.

**CONFIDENTIAL**

**Listing 9: Dates of Treatments and Completion/Withdrawal**  
Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.  
A meta-analysis of results from two randomized clinical trials

(USA)

Subject ID	Group	Start date of treatment	End date of treatment	End Week on Treatment	Completed Study?	Primary Reason for Discontinuation
R1001	Active	2009-03-02T09:55	2009-05-11	11	Yes	COMPLETED
R1002	Placebo	2009-03-02T16:12	2009-05-08	10	Yes	COMPLETED
R1003	Active	2009-03-03T10:44	2009-03-03	1	No	SORE GUMS
R1004	Placebo	2009-03-09T15:41	2009-05-18	11	Yes	COMPLETED
R1005	Active	2009-03-10T10:17	2009-05-22	11	Yes	COMPLETED
R1006	Placebo	2009-03-11T17:10	2009-05-22	11	Yes	COMPLETED
R1007	Active	2009-03-13T11:12	2009-05-22	11	Yes	COMPLETED
R1008	Placebo	2009-03-16T10:47	2009-04-27	7	No	CONSENT WITHDRAWN
R1009	Active	2009-03-16T11:43	2009-04-27	7	No	CONSENT WITHDRAWN
R1010	Active	2009-03-24T08:45	2009-06-03	11	Yes	COMPLETED
R1011	Placebo	2009-04-16T11:14	2009-06-26	11	Yes	COMPLETED
R1012	Placebo	2009-04-16T13:20	2009-06-29	11	Yes	COMPLETED
R1013	Placebo	2009-04-22T10:01	2009-07-01	11	Yes	COMPLETED
R1014	Placebo	2009-04-22T10:17	2009-04-22	1	No	LOST TO FOLLOW-UP
R1015	Active	2009-04-28T12:45	2009-07-10	11	Yes	COMPLETED
R1016	Active	2009-05-15T09:31	2009-07-24	11	Yes	COMPLETED
R1017	Active	2009-05-15T10:32	2009-07-24	11	Yes	COMPLETED
R1018	Placebo	2009-05-15T11:20	2009-06-30	7	No	CONSENT WITHDRAWN
R1019	Active	2009-05-21T12:31	2009-08-05	11	Yes	COMPLETED
R1020	Placebo	2009-06-04T11:41	2009-08-13	11	No	CONSENT WITHDRAWN
R1021	Placebo	2009-06-04T14:02	2009-08-13	11	Yes	COMPLETED
R1022	Active	2009-06-09T10:44	2009-08-20	11	No	SUBJECT COMPLETED STUDY BUT WAS OUT OF WINDOW
R1023	Placebo	2009-06-18T13:50	2009-06-18	1	No	CONSENT WITHDRAWN
R1024	Active	2009-06-23T09:53	2009-08-31	10	Yes	COMPLETED
R1025	Active	2009-06-25T10:56	2009-09-03	11	Yes	COMPLETED
R1026	Active	2009-06-25T13:38	2009-09-03	11	Yes	COMPLETED
R1027	Placebo	2009-07-02T08:40	2009-07-02	1	No	CONSENT WITHDRAWN
R1028	Placebo	2009-07-02T11:07	2009-09-24	13	No	SUBJECT COMPLETED BUT WAS OUT OF WINDOW
R1029	Active	2009-07-06T08:56	2009-08-17	7	No	VAGINAL BLEEDING WITH PREGNANCY
R1030	Placebo	2009-07-16T10:35	2009-09-24	11	Yes	COMPLETED
R1031	Active	2009-07-16T11:08	2009-08-31	7	Yes	COMPLETED
R1032	Active	2009-07-17T10:35	2009-09-25	11	No	CONSENT WITHDRAWN
R1033	Placebo	2009-07-21T15:55	2009-07-21	1	No	CONSENT WITHDRAWN
R1034	Placebo	2009-07-30T14:49	2009-10-08	11	Yes	COMPLETED
R1035	Active	2009-07-30T15:39	2009-10-08	11	Yes	COMPLETED
R1036	Placebo	2009-07-30T15:45	2009-10-08	11	No	LOST TO FOLLOW-UP
R1037	Active	2009-07-31T08:47	2009-10-09	11	Yes	COMPLETED
R5001	Placebo	2009-06-30T11:32	2009-09-08	11	Yes	COMPLETED
R5002	Active	2009-06-30T12:37	2009-09-08	11	Yes	COMPLETED
R5003	Placebo	2009-06-30T12:56	2009-09-08	11	Yes	COMPLETED
R5004	Active	2009-07-06T10:25	2009-09-14	11	Yes	COMPLETED
R5005	Placebo	2009-07-06T11:04	2009-08-17	7	No	LOST TO FOLLOW-UP
R5006	Active	2009-07-06T11:30	2009-09-14	11	Yes	COMPLETED
R5007	Active	2009-07-06T11:55	2009-07-06	1	No	LOST TO FOLLOW-UP
R5008	Placebo	2009-07-07T12:10	2009-09-14	10	Yes	COMPLETED
R5009	Placebo	2009-07-07T12:22	2009-07-07	1	No	TERMINATED BY SPONSOR
R5010	Active	2009-07-07T11:05	2009-07-07	1	No	CONSENT WITHDRAWN
R5011	Active	2009-07-07T10:30	2009-09-14	10	Yes	COMPLETED
R5012	Placebo	2009-07-10T11:13	2009-07-10	1	No	CONSENT WITHDRAWN

**CONFIDENTIAL**

**Listing 9: Dates of Treatments and Completion/Withdrawal**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")

on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**(USA)**

Subject ID	Group	Start date of treatment	End date of treatment	End Week on Treatment	Completed Study?	Primary Reason for Discontinuation
R5013	Active	2009-07-13T10:31	2009-09-21	11	Yes	COMPLETED
R5014	Placebo	2009-07-14T13:10	2009-09-22	11	No	CONSENT WITHDRAWN
R5015	Placebo	2009-07-14T13:00	2009-09-21	10	Yes	COMPLETED
R5016	Placebo	2009-07-17T09:48	2009-07-17	1	No	CONSENT WITHDRAWN
R5017	Active	2009-07-17T10:28	2009-07-17	1	No	CONSENT WITHDRAWN
R5018	Active	2009-07-17T11:36	2009-09-28	11	Yes	COMPLETED
R5019	Placebo	2009-07-21T09:32	2009-09-28	10	Yes	COMPLETED
R5020	Active	2009-07-21T10:56	2009-09-29	11	Yes	COMPLETED
R5021	Placebo	2009-07-21T11:53	2009-09-28	10	Yes	COMPLETED
R5022	Active	2009-07-24T11:05	2009-10-05	11	Yes	COMPLETED
R5023	Active	2009-07-24T12:45	2009-10-05	11	Yes	COMPLETED
R5024	Placebo	2009-07-28T10:36	2009-07-28	1	No	LOST TO FOLLOW-UP
R5025	Placebo	2009-07-28T11:25	2009-10-05	10	Yes	COMPLETED
R5026	Placebo	2009-07-28T11:59	2009-07-28	1	No	LOST TO FOLLOW-UP
R5027	Active	2009-07-28T12:54	2009-10-05	10	No	PREGNANCY
R5028	Active	2009-07-29T11:33	2009-10-07	11	No	SUBJECT COMPLETED BUT WAS OUT OF WINDOW.
R3001	Active	2009-03-02T09:14	2009-04-10	6	Yes	COMPLETED
R3002	Placebo	2009-03-02T09:38	2009-05-11	11	Yes	COMPLETED
R3003	Active	2009-03-02T10:24	2009-05-11	11	Yes	COMPLETED
R3004	Placebo	2009-03-02T12:27	2009-05-11	11	Yes	COMPLETED
R3005	Placebo	2009-03-03T08:42	2009-05-13	11	No	CONSENT WITHDRAWN
R3006	Active	2009-03-03T10:38	2009-05-11	10	Yes	COMPLETED
R3007	Placebo	2009-03-03T10:48	2009-05-15	11	Yes	COMPLETED
R3008	Placebo	2009-03-03T12:40	2009-05-12	11	Yes	COMPLETED
R3009	Active	2009-03-10T10:34	2009-04-21	7	No	GLOSSITIS AND PHARYNGITIS
R3010	Placebo	2009-03-10T15:10	2009-05-19	11	Yes	COMPLETED
R3011	Active	2009-03-25T12:14	2009-05-28	10	Yes	COMPLETED
R3012	Active	2009-03-30T13:00	2009-03-30	1	No	ACNE VULGARIS, DIARRHEA, DYSPEPSIA
R3013	Active	2009-04-06T10:10	2009-06-17	11	Yes	COMPLETED
R3014	Placebo	2009-04-07T09:44	2009-05-21	7	No	CONSENT WITHDRAWN
R3015	Placebo	2009-04-07T10:26	2009-04-07	1	No	CONSENT WITHDRAWN
R3016	Active	2009-04-14T12:02	2009-06-23	11	Yes	COMPLETED
R3017	Active	2009-04-15T11:09	2009-04-15	1	No	CONSENT WITHDRAWN
R3018	Placebo	2009-04-15T12:09	2009-06-01	7	No	LOST TO FOLLOW-UP
R3019	Placebo	2009-04-28T10:39	2009-07-07	11	Yes	COMPLETED
R3020	Active	2009-04-28T10:48	2009-07-08	11	Yes	COMPLETED
R3021	Active	2009-05-05T08:43	2009-05-05	1	No	CONSENT WITHDRAWN
R3022	Placebo	2009-05-05T10:23	2009-06-16	7	Yes	COMPLETED
R3023	Placebo	2009-05-05T13:09	2009-05-05	1	No	CONSENT WITHDRAWN
R3024	Active	2009-05-12T10:32	2009-05-12	1	No	CONSENT WITHDRAWN
R3025	Placebo	2009-05-12T11:41	2009-06-24	7	No	DYSESTHESIA
R3026	Active	2009-05-13T11:16	2009-07-21	10	Yes	COMPLETED
R3027	Active	2009-05-13T12:09	2009-07-27	11	No	LOST TO FOLLOW-UP
R3028	Placebo	2009-05-19T08:03	2009-07-31	11	No	SUBJECT COMPLETED BUT WAS OUT OF WINDOW
R3029	Placebo	2009-05-19T10:52	2009-06-30	7	No	LOST TO FOLLOW-UP
R3030	Active	2009-05-19T11:19	2009-05-19	1	No	LOST TO FOLLOW-UP
R3031	Active	2009-05-19T13:40	2009-05-19	1	Yes	COMPLETED
R3032	Placebo	2009-05-20T12:25	2009-05-20	1	No	CONSENT WITHDRAWN
R2001	Active	2009-03-13T09:27	2009-03-13	1	No	CONSENT WITHDRAWN

**CONFIDENTIAL**

**Listing 9: Dates of Treatments and Completion/Withdrawal**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**(USA)**

Subject ID	Group	Start date of treatment	End date of treatment	End Week on Treatment	Completed Study?	Primary Reason for Discontinuation
R2002	Active	2009-03-17T14:41	2009-05-29	11	Yes	COMPLETED
R2003	Active	2009-03-18T14:17	2009-05-27	11	Yes	COMPLETED
R2004	Placebo	2009-03-23T08:50	2009-03-23	1	No	CONSENT WITHDRAWN
R2005	Placebo	2009-03-24T12:13	2009-06-08	11	Yes	COMPLETED
R2006	Placebo	2009-03-26T07:52	2009-06-05	11	No	CONSENT WITHDRAWN
R2007	Placebo	2009-04-16T10:08	2009-06-25	11	Yes	COMPLETED
R2008	Active	2009-04-20T10:49	2009-06-04	7	No	LOST TO FOLLOW-UP
R2009	Placebo	2009-04-21T10:55	2009-06-30	11	Yes	COMPLETED
R2010	Active	2009-04-22T10:40	2009-07-01	11	Yes	COMPLETED
R2011	Placebo	2009-04-23T08:41	2009-07-02	11	Yes	COMPLETED
R2012	Active	2009-04-27T08:41	2009-07-06	11	Yes	COMPLETED
R2013	Active	2009-04-28T10:53	2009-07-07	11	Yes	COMPLETED
R2014	Placebo	2009-05-04T10:59	2009-07-14	11	Yes	COMPLETED
R2015	Active	2009-05-05T08:52	2009-07-15	11	Yes	COMPLETED
R2016	Placebo	2009-05-08T11:00	2009-07-17	11	Yes	COMPLETED
R2017	Active	2009-05-08T15:46	2009-07-17	11	Yes	COMPLETED
R2018	Placebo	2009-05-22T14:48	2009-07-02	6	No	CONSENT WITHDRAWN
R2019	Placebo	2009-05-26T11:41	2009-08-03	10	Yes	COMPLETED
R2020	Active	2009-05-27T09:34	2009-07-09	7	No	LOST TO FOLLOW-UP
R2021	Active	2009-06-05T14:11	2009-08-14	11	Yes	COMPLETED
R2022	Placebo	2009-06-29T12:52	2009-08-14	7	No	SUBJECT COMPLETED, BUT WAS OUT OF WINDOW
R2023	Placebo	2009-07-02T09:48	2009-09-11	11	No	LOST TO FOLLOW-UP
R2024	Active	2009-07-09T10:36	2009-09-18	11	No	SUBJECT COMPLETED, BUT WAS OUT OF WINDOW
R2025	Active	2009-07-13T14:01	2009-09-21	11	No	LOST TO FOLLOW-UP
R2026	Active	2009-07-14T13:52	2009-09-23	11	Yes	COMPLETED
R2027	Active	2009-07-15T09:00	2009-09-21	10	Yes	COMPLETED
R2028	Placebo	2009-07-22T11:04	2009-09-30	11	Yes	COMPLETED
R2029	Placebo	2009-07-23T12:10	2009-10-01	11	Yes	COMPLETED
R2030	Placebo	2009-07-29T08:46	2009-07-29	1	No	CONSENT WITHDRAWN
R2031	Placebo	2009-07-31T08:55	2009-10-08	10	Yes	COMPLETED
R2032	Active	2009-08-05T15:49	2009-10-14	11	No	LOST TO FOLLOW-UP
R4001	Placebo	2009-03-02T10:04	2009-05-11	11	No	CONSENT WITHDRAWN
R4002	Active	2009-03-02T10:18	2009-05-11	11	Yes	COMPLETED
R4003	Placebo	2009-03-02T16:27	2009-05-11	11	Yes	COMPLETED
R4004	Active	2009-03-02T16:33	2009-03-02	1	No	CONSENT WITHDRAWN
R4005	Active	2009-03-03T17:03	2009-05-12	11	Yes	COMPLETED
R4006	Placebo	2009-03-11T08:28	2009-03-11	1	No	CONSENT WITHDRAWN
R4007	Active	2009-03-11T09:04	2009-05-26	11	Yes	COMPLETED
R4008	Active	2009-03-11T09:18	2009-05-20	11	Yes	COMPLETED
R4009	Placebo	2009-03-11T09:41	2009-05-20	11	No	CONSENT WITHDRAWN
R4010	Placebo	2009-03-11T10:25	2009-05-20	11	Yes	COMPLETED
R4011	Placebo	2009-03-11T10:45	2009-05-20	11	Yes	COMPLETED
R4012	Active	2009-03-11T10:54	2009-05-20	11	Yes	COMPLETED
R4013	Active	2009-03-11T11:19	2009-03-11	1	No	CONSENT WITHDRAWN
R4014	Placebo	2009-03-11T12:25	2009-05-22	11	No	CONSENT WITHDRAWN
R4015	Placebo	2009-03-11T12:57	2009-05-20	11	Yes	COMPLETED
R4016	Active	2009-03-13T09:02	2009-05-22	11	Yes	COMPLETED
R4017	Active	2009-03-13T15:08	2009-05-22	11	Yes	COMPLETED
R4018	Placebo	2009-03-13T16:38	2009-05-22	11	Yes	COMPLETED

**CONFIDENTIAL**

**Listing 9: Dates of Treatments and Completion/Withdrawal**  
Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials

**(USA)**

<b>Subject ID</b>	<b>Group</b>	<b>Start date of treatment</b>	<b>End date of treatment</b>	<b>End Week on Treatment</b>	<b>Completed Study?</b>	<b>Primary Reason for Discontinuation</b>
R4019	Placebo	2009-03-30T10:01	2009-06-08	11	Yes	COMPLETED
R4020	Active	2009-03-30T10:57	2009-06-08	11	Yes	COMPLETED
R4021	Placebo	2009-03-30T16:09	2009-06-08	11	No	CONSENT WITHDRAWN
R4022	Active	2009-03-30T17:00	2009-06-12	11	Yes	COMPLETED
R4023	Placebo	2009-03-30T18:01	2009-06-08	11	Yes	COMPLETED
R4024	Active	2009-03-31T14:58	2009-03-31	1	No	CONSENT WITHDRAWN
R4025	Active	2009-04-01T18:23	2009-04-01	1	No	DID NOT LIKE THE TASTE OF THE PRODUCT
R4026	Placebo	2009-04-10T12:37	2009-06-19	11	Yes	COMPLETED
R4027	Active	2009-04-15T10:03	2009-06-24	11	Yes	COMPLETED
R4028	Active	2009-04-23T09:55	2009-07-08	11	Yes	COMPLETED
R4029	Placebo	2009-04-23T10:14	2009-07-02	11	Yes	COMPLETED
R4030	Placebo	2009-04-23T10:41	2009-06-04	7	No	CONSENT WITHDRAWN
R4031	Placebo	2009-04-23T11:24	2009-04-23	1	No	CONSENT WITHDRAWN
R4032	Placebo	2009-04-23T11:41	2009-07-02	11	Yes	COMPLETED
R4033	Active	2009-04-27T13:25	2009-07-07	11	Yes	COMPLETED
R4034	Active	2009-04-28T13:28	2009-04-28	1	No	CONSENT WITHDRAWN
R4035	Active	2009-05-04T14:04	2009-06-15	7	Yes	COMPLETED
R4036	Placebo	2009-05-05T13:13	2009-07-17	11	No	SUBJECT COMPLETED BUT WAS OUTSIDE OF WINDOW
R4037	Placebo	2009-05-05T13:13	2009-07-14	11	Yes	COMPLETED
R4038	Placebo	2009-05-05T13:13	2009-07-14	11	Yes	COMPLETED
R4039	Active	2009-05-05T13:13	2009-07-14	11	Yes	COMPLETED
R4040	Active	2009-05-05T13:39	2009-07-14	11	Yes	COMPLETED
R4041	Placebo	2009-05-05T14:15	2009-07-13	10	Yes	COMPLETED
R4042	Active	2009-05-05T15:15	2009-07-14	11	Yes	COMPLETED
R4043	Active	2009-05-05T14:35	2009-05-05	1	No	CONSENT WITHDRAWN
R4044	Active	2009-05-05T14:56	2009-06-19	7	No	JOB TRANSFER TO OUT OF TOWN
R4045	Placebo	2009-05-05T15:34	2009-07-14	11	Yes	COMPLETED
R4046	Placebo	2009-05-07T16:25	2009-06-18	7	No	INCREASE IN SMOKING CIGARETTES
R4047	Placebo	2009-05-13T11:54	2009-07-22	11	Yes	COMPLETED
R4048	Active	2009-05-20T14:53	2009-06-30	6	No	CONSENT WITHDRAWN
R4049	Active	2009-05-22T10:09	2009-07-31	11	Yes	COMPLETED
R4050	Placebo	2009-06-02T13:02	2009-08-11	11	Yes	COMPLETED
R4051	Active	2009-06-02T14:06	2009-08-11	11	Yes	COMPLETED
R4052	Placebo	2009-06-02T14:06	2009-08-11	11	Yes	COMPLETED
R4053	Active	2009-06-02T14:06	2009-06-02	1	No	CONSENT WITHDRAWN
R4054	Placebo	2009-06-04T09:50	2009-08-18	11	No	CONSENT WITHDRAWN
R4055	Active	2009-06-04T10:10	2009-08-13	11	Yes	COMPLETED
R4056	Active	2009-06-08T10:13	2009-08-17	11	No	CONSENT WITHDRAWN
R4057	Active	2009-06-11T12:24	2009-08-21	11	No	SUBJECT COMPLETED BUT WAS OUT OF WINDOW.
R4058	Placebo	2009-06-11T15:33	2009-08-20	11	Yes	COMPLETED
R4059	Placebo	2009-06-11T15:45	2009-08-19	10	Yes	COMPLETED
R4060	Placebo	2009-06-12T11:40	2009-08-21	11	Yes	COMPLETED
R4061	Active	2009-06-18T08:36	2009-06-18	1	No	CONSENT WITHDRAWN
R4062	Placebo	2009-06-18T14:33	2009-08-27	11	Yes	COMPLETED
R4063	Active	2009-06-18T14:58	2009-08-27	11	Yes	COMPLETED
R4064	Placebo	2009-06-18T15:16	2009-09-02	11	Yes	COMPLETED
R4065	Active	2009-06-18T15:45	2009-08-03	7	Yes	COMPLETED
R4066	Placebo	2009-06-18T16:33	2009-08-04	7	No	CONSENT WITHDRAWN

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**Listing 9: Dates of Treatments and Completion/Withdrawal**

Study: SM 11-01    Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials

**(USA)**

<b>Subject ID</b>	<b>Group</b>	<b>Start date of treatment</b>	<b>End date of treatment</b>	<b>End Week on Treatment</b>	<b>Completed Study?</b>	<b>Primary Reason for Discontinuation</b>
R4067	Placebo	2009-06-18T16:44	2009-06-18	1	No	DUE TO NO TRANSPORTATION
R4068	Active	2009-06-19T11:21	2009-08-25	10	Yes	COMPLETED
R4069	Active	2009-06-23T14:21	2009-08-06	7	Yes	COMPLETED
R4070	Placebo	2009-06-26T12:15	2009-09-09	11	No	SUBJECT COMPLETED BUT WAS OUT OF WINDOW
R4071	Active	2009-06-26T12:32	2009-09-03	10	Yes	COMPLETED
R4072	Placebo	2009-06-26T13:01	2009-09-04	11	Yes	COMPLETED
R4073	Active	2009-06-29T09:50	2009-06-29	1	No	LOST TO FOLLOWUP - WEEK 8 VISIT OUT OF WINDOW
R4074	Placebo	2009-06-29T11:08	2009-06-29	1	No	CONSENT WITHDRAWN
R4075	Active	2009-06-29T11:27	2009-09-09	11	No	CONSENT WITHDRAWN
R4076	Placebo	2009-06-29T11:39	2009-06-29	1	No	CONSENT WITHDRAWN
R4077	Active	2009-06-29T12:15	2009-08-10	7	No	CONSENT WITHDRAWN
R4078	Placebo	2009-06-29T12:54	2009-08-10	7	No	CONSENT WITHDRAWN
R4079	Placebo	2009-06-29T12:54	2009-09-15	12	Yes	COMPLETED
R4080	Active	2009-06-29T13:10	2009-06-29	1	No	LOST TO FOLLOW-UP
R4081	Active	2009-06-29T15:25	2009-06-29	1	No	CONSENT WITHDRAWN
R4082	Placebo	2009-06-29	2009-06-29	1	No	CONSENT WITHDRAWN
R4083	Active	2009-06-29T16:05	2009-09-08	11	Yes	COMPLETED
R4084	Placebo	2009-07-01T15:33	2009-08-17	7	No	LOST TO FOLLOW-UP
R4085	Active	2009-07-02T09:45	2009-07-02	1	No	LOST TO FOLLOW-UP
R4086	Active	2009-07-02T10:04	2009-08-13	7	No	LOST TO FOLLOW-UP
R4087	Placebo	2009-07-02T10:04	2009-07-02	1	No	CONSENT WITHDRAWN
R4088	Placebo	2009-07-02T12:15	2009-08-11	6	No	CONSENT WITHDRAWN
R4089	Placebo	2009-07-02T12:26	2009-09-10	11	No	CONSENT WITHDRAWN
R4090	Active	2009-07-02T13:30	2009-09-10	11	Yes	COMPLETED
R4091	Active	2009-07-02T13:30	2009-09-16	11	No	SUBJECT COMPLETED BUT WAS OUTSIDE THE WINDOW
R4092	Active	2009-07-02T13:55	2009-09-10	11	Yes	COMPLETED
R4093	Placebo	2009-07-08T11:19	2009-09-16	11	No	SUBJECT COMPLETED BUT WAS OUTSIDE THE WINDOW
R4094	Placebo	2009-07-08T11:35	2009-09-16	11	No	SUBJECT COMPLETED BUT WAS OUT OF WINDOW
R4095	Active	2009-07-08T12:08	2009-07-08	1	No	SUBJECT INCARCERATED
R4096	Placebo	2009-07-08T12:37	2009-09-16	11	No	SUBJECT COMPLETED BUT OUTSIDE THE WINDOW
R4097	Active	2009-07-08T12:59	2009-09-16	11	Yes	COMPLETED
R4098	Placebo	2009-07-08T13:37	2009-07-08	1	No	CONSENT WITHDRAWN
R4099	Active	2009-07-08T13:55	2009-09-14	10	No	SUBJECT COMPLETED BUT WAS OUT OF WINDOW
R4100	Active	2009-07-08T14:32	2009-09-16	11	Yes	COMPLETED
R4101	Placebo	2009-07-08T14:32	2009-07-08	1	No	LOST TO FOLLOW-UP
R4102	Placebo	2009-07-08T14:41	2009-07-08	1	Yes	COMPLETED
R4103	Placebo	2009-07-10T13:06	2009-08-24	7	No	CONSENT WITHDRAWN
R4104	Placebo	2009-07-17T08:33	2009-07-17	1	No	LOST TO FOLLOW-UP
R4105	Active	2009-07-23T08:31	2009-10-01	11	Yes	COMPLETED
R4106	Active	2009-07-23T08:56	2009-10-01	11	No	CONSENT WITHDRAWN
R4107	Active	2009-07-23T09:48	2009-10-01	11	Yes	COMPLETED
R4108	Placebo	2009-07-23T10:05	2009-07-23	1	No	CONSENT WITHDRAWN
R4109	Placebo	2009-07-23T10:05	2009-07-23	1	No	DISCONTINUED DUE TO NONCOMPLIANCE-WOULD NOT RETURN PHONE CALLS

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**Listing 9: Dates of Treatments and Completion/Withdrawal**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials

**(USA)**

<b>Subject ID</b>	<b>Group</b>	<b>Start date of treatment</b>	<b>End date of treatment</b>	<b>End Week on Treatment</b>	<b>Completed Study?</b>	<b>Primary Reason for Discontinuation</b>
R4110	Active	2009-07-23T10:30	2009-07-23	1	No	CONSENT WITHDRAWN
R4111	Placebo	2009-07-23T12:05	2009-07-23	1	No	LOST TO FOLLOW-UP
R4112	Active	2009-07-23T11:57	2009-07-23	1	No	CONSENT WITHDRAWN
R4113	Active	2009-07-23T11:57	2009-10-01	11	Yes	COMPLETED
R4114	Placebo	2009-07-23T12:05	2009-10-01	11	Yes	COMPLETED
R4115	Active	2009-07-23T13:05	2009-09-09	7	No	LOST TO FOLLOW-UP
R4116	Placebo	2009-07-23T13:29	2009-10-05	11	Yes	COMPLETED
R4117	Active	2009-07-23T14:18	2009-10-01	11	Yes	COMPLETED
R4118	Placebo	2009-07-23T14:45	2009-10-02	11	Yes	COMPLETED
R4119	Placebo	2009-07-23T15:25	2009-10-01	11	No	SUBJECT COMPLETED BUT OUTSIDE THE WINDOW
R4120	Active	2009-07-23T16:11	2009-10-01	11	Yes	COMPLETED
R4121	Placebo	2009-07-30T15:10	2009-07-30	1	No	LOST TO FOLLOW-UP

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**Listing 10: Outcome**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials

**(Serbia)**

Subject ID	Group	Primary: Smoking cessation 25-48 weeks	Smoke-free week 24	Smoke-free week 36	Smoke-free week 48	Cessation weeks 45-48	Cessation weeks 37-48
1001	Placebo	No	No	No	No	No	No
1002	Placebo	No	No	No	No	No	No
1003	Active	No	No	No	No	No	No
1004	Active	No	No	No	No	No	No
1005	Active	No	No	No	No	No	No
1006	Placebo	No	No	No	No	No	No
1007	Active	No	No	No	No	No	No
1008	Active	No	No	No	No	No	No
1009	Placebo	No	No	No	No	No	No
1010	Placebo	No	No	No	No	No	No
1011	Active	No	No	No	No	No	No
1012	Placebo	No	No	No	No	No	No
1013	Active	No	No	No	No	No	No
1014	Active	No	No	No	No	No	No
1015	Active	No	No	No	No	No	No
1016	Placebo	No	No	No	No	No	No
1017	Placebo	No	No	No	No	No	No
1018	Placebo	No	No	No	No	No	No
1019	Active	No	No	No	No	No	No
1020	Placebo	No	No	No	No	No	No
1021	Active	No	No	No	No	No	No
1022	Placebo	No	No	No	No	No	No
1023	Active	No	No	No	No	No	No
1024	Placebo	No	No	No	No	No	No
1025	Placebo	No	No	No	No	No	No
1026	Placebo	No	No	No	No	No	No
1027	Placebo	No	No	No	No	No	No
1028	Active	No	No	No	No	No	No
1029	Active	No	No	No	No	No	No
1030	Active	No	No	No	No	No	No
1031	Active	No	Yes	No	No	No	No
1032	Active	No	No	No	No	No	No
1033	Placebo	No	No	No	No	No	No
1034	Active	No	No	No	No	No	No
1035	Placebo	No	No	No	No	No	No
1036	Placebo	No	No	No	No	No	No
1037	Placebo	No	No	No	Yes	No	No
1038	Active	Yes	Yes	Yes	Yes	Yes	Yes
1039	Placebo	No	No	No	No	No	No
1040	Active	No	No	No	No	No	No
1041	Placebo	No	No	No	No	No	No
1042	Active	No	No	No	No	No	No
1043	Placebo	No	No	No	No	No	No
1044	Active	No	No	No	No	No	No
1045	Active	No	No	No	No	No	No
1046	Placebo	No	No	No	No	No	No
1047	Active	No	No	No	No	No	No
1048	Placebo	No	No	No	No	No	No
1049	Placebo	No	No	No	No	No	No
1050	Active	No	No	No	No	No	No
1205	Placebo	No	No	No	No	No	No

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**Listing 10: Outcome**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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**(Serbia)**

Subject ID	Group	Primary: Smoking cessation 25-48 weeks	Smoke-free week 24	Smoke-free week 36	Smoke-free week 48	Cessation weeks 45-48	Cessation weeks 37-48
1206	Placebo	No	No	No	No	No	No
1207	Active	No	No	No	No	No	No
1208	Active	No	No	No	No	No	No
1209	Active	No	No	No	No	No	No
1210	Placebo	No	No	No	No	No	No
1211	Active	No	No	No	No	No	No
1212	Active	No	No	No	No	No	No
1213	Placebo	No	No	No	No	No	No
1214	Placebo	No	No	No	No	No	No
1215	Active	No	No	No	No	No	No
1216	Placebo	No	No	No	No	No	No
1217	Active	No	No	No	No	No	No
1218	Active	No	No	No	No	No	No
1219	Active	No	No	No	No	No	No
1220	Placebo	No	No	No	No	No	No
1221	Placebo	No	No	No	No	No	No
1222	Placebo	No	No	No	No	No	No
1223	Active	No	No	No	No	No	No
1224	Placebo	No	No	No	No	No	No
1225	Active	No	No	No	No	No	No
1226	Placebo	No	No	No	No	No	No
1227	Active	No	No	No	No	No	No
1228	Placebo	No	No	No	No	No	No
1229	Placebo	No	No	No	No	No	No
1230	Placebo	No	No	No	No	No	No
1231	Placebo	No	No	No	No	No	No
1232	Active	No	No	No	No	No	No
1233	Active	No	No	No	No	No	No
1234	Active	No	No	No	No	No	No
1235	Active	No	No	No	No	No	No
1236	Active	No	No	No	No	No	No
1237	Placebo	No	No	No	No	No	No
1238	Active	No	No	No	No	No	No
1239	Placebo	No	No	No	No	No	No
1240	Placebo	No	No	No	No	No	No
1241	Placebo	No	No	No	No	No	No
1242	Active	No	No	No	No	No	No
1243	Placebo	No	No	No	No	No	No
1244	Active	No	No	No	No	No	No
1245	Placebo	No	No	No	No	No	No
1246	Active	No	No	Yes	Yes	Yes	Yes
1247	Placebo	No	No	No	No	No	No
1325	Placebo	Yes	Yes	Yes	Yes	Yes	Yes
1326	Placebo	No	No	No	No	No	No
1327	Active	No	No	No	No	No	No
1328	Active	No	No	Yes	Yes	Yes	Yes
1329	Active	No	No	No	No	No	No
1330	Placebo	No	No	No	No	No	No
1331	Active	No	No	No	Yes	Yes	Yes
1332	Active	No	No	No	No	No	No
1333	Placebo	No	No	No	No	No	No

**CONFIDENTIAL**

**Listing 10: Outcome**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

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**(Serbia)**

Subject ID	Group	Primary: Smoking cessation 25-48 weeks	Smoke-free week 24	Smoke-free week 36	Smoke-free week 48	Cessation weeks 45-48	Cessation weeks 37-48
1334	Placebo	No	No	No	No	No	No
1335	Active	No	No	No	No	No	No
1336	Placebo	No	No	No	No	No	No
1337	Active	No	No	No	No	No	No
1338	Active	No	No	No	Yes	Yes	No
1339	Active	No	No	No	No	No	No
1340	Placebo	No	No	No	No	No	No
1341	Placebo	No	No	No	No	No	No
1342	Placebo	No	No	No	No	No	No
1343	Active	No	No	No	Yes	Yes	Yes
1344	Placebo	No	No	No	Yes	Yes	No
1345	Active	No	No	Yes	Yes	Yes	Yes
1346	Placebo	No	No	No	No	No	No
1347	Active	No	No	No	No	No	No
1348	Placebo	No	No	No	No	No	No
1349	Placebo	No	No	No	No	No	No
2001	Placebo	No	No	No	No	No	No
2002	Placebo	No	No	No	No	No	No
2003	Active	No	No	No	No	No	No
2004	Active	No	No	No	No	No	No
2005	Active	No	No	No	No	No	No
2006	Placebo	No	No	No	No	No	No
2007	Active	No	No	No	No	No	No
2008	Active	No	No	No	No	No	No
2009	Placebo	No	No	No	No	No	No
2010	Placebo	No	No	No	No	No	No
2011	Active	No	No	No	No	No	No
2012	Placebo	No	No	No	No	No	No
2013	Active	No	No	No	No	No	No
2014	Active	No	No	No	No	No	No
2015	Active	No	No	No	No	No	No
2016	Placebo	No	No	No	Yes	Yes	No
2017	Placebo	No	No	No	No	No	No
2018	Placebo	No	No	No	No	No	No
2019	Active	No	No	No	No	No	No
2020	Placebo	No	No	No	No	No	No
2021	Active	No	No	No	No	No	No
2022	Placebo	No	No	No	No	No	No
2023	Active	No	No	No	No	No	No
2024	Placebo	No	No	No	No	No	No
2025	Placebo	No	No	No	No	No	No
2026	Placebo	No	No	No	Yes	Yes	No
2027	Placebo	No	No	No	No	No	No
2028	Active	No	No	Yes	Yes	Yes	No
2029	Active	No	No	No	No	No	No
2030	Active	No	No	No	No	No	No
2031	Active	No	No	No	No	No	No
2032	Active	No	No	No	No	No	No
2033	Placebo	No	No	No	No	No	No
2034	Active	No	No	No	No	No	No
2035	Placebo	No	No	No	No	No	No

**CONFIDENTIAL**

**Listing 10: Outcome**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**(Serbia)**

Subject ID	Group	Primary: Smoking cessation 25-48 weeks	Smoke-free week 24	Smoke-free week 36	Smoke-free week 48	Cessation weeks 45-48	Cessation weeks 37-48
2036	Placebo	No	No	No	No	No	No
2037	Placebo	No	No	No	No	No	No
2038	Active	No	No	No	No	No	No
2039	Placebo	No	No	No	No	No	No
2040	Active	No	No	No	No	No	No
2041	Placebo	No	No	No	No	No	No
2042	Active	No	No	No	No	No	No
2043	Placebo	No	No	No	No	No	No
2044	Active	No	No	No	No	No	No
2045	Active	No	No	No	No	No	No
2046	Placebo	No	No	No	No	No	No
2047	Active	No	No	Yes	Yes	Yes	No
2048	Placebo	No	No	Yes	Yes	Yes	Yes
2049	Placebo	No	No	No	No	No	No
2050	Active	No	No	No	No	No	No
2205	Active	No	No	No	No	No	No
2206	Placebo	No	No	No	No	No	No
2207	Placebo	No	No	No	No	No	No
2208	Active	No	No	No	No	No	No
2209	Active	No	No	No	No	No	No
2210	Placebo	No	No	Yes	Yes	Yes	Yes
2211	Placebo	No	No	No	No	No	No
2212	Placebo	No	No	No	No	No	No
2213	Active	No	No	No	No	No	No
2214	Active	No	No	No	No	No	No
2215	Active	No	No	No	No	No	No
2216	Placebo	No	No	No	No	No	No
2217	Active	No	No	No	Yes	Yes	No
2218	Placebo	No	No	No	No	No	No
2219	Active	No	No	No	No	No	No
2220	Placebo	No	No	No	No	No	No
2221	Placebo	No	No	No	Yes	Yes	No
2222	Active	No	No	No	No	No	No
2223	Placebo	No	No	No	No	No	No
2224	Placebo	No	No	No	No	No	No
2225	Placebo	No	No	No	No	No	No
2226	Active	No	No	No	No	No	No
2227	Active	No	No	No	No	No	No
2228	Active	No	No	No	No	No	No
2229	Placebo	No	No	No	No	No	No
2230	Active	No	No	No	No	No	No
2231	Active	No	No	No	No	No	No
2232	Placebo	No	No	No	No	No	No
2233	Placebo	No	No	No	No	No	No
2234	Active	No	No	No	No	No	No
2235	Placebo	No	No	No	No	No	No
2236	Placebo	No	No	No	Yes	No	No
2237	Placebo	No	No	No	No	No	No
2238	Active	No	No	No	Yes	No	No
2239	Active	No	No	No	No	No	No
2240	Active	No	No	No	No	No	No

**CONFIDENTIAL**

**Listing 10: Outcome**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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**(Serbia)**

Subject ID	Group	Primary: Smoking cessation 25-48 weeks	Smoke-free week 24	Smoke-free week 36	Smoke-free week 48	Cessation weeks 45-48	Cessation weeks 37-48
2241	Active	No	No	No	No	No	No
2242	Active	No	No	Yes	Yes	Yes	Yes
2243	Placebo	No	No	No	No	No	No
2244	Placebo	No	No	No	No	No	No
2245	Active	Yes	Yes	Yes	Yes	Yes	Yes
2246	Placebo	No	No	No	No	No	No
2247	Active	No	No	No	No	No	No
2248	Active	No	No	No	No	No	No
2249	Placebo	No	No	No	No	No	No
2250	Placebo	No	No	No	Yes	No	No
2251	Active	No	No	No	No	No	No
2252	Placebo	No	No	No	No	No	No
2253	Active	No	No	No	No	No	No
2254	Placebo	No	No	No	No	No	No
2255	Active	No	No	No	No	No	No
2256	Placebo	No	No	No	Yes	Yes	No
2257	Active	Yes	Yes	Yes	Yes	Yes	Yes
2258	Placebo	No	No	No	Yes	Yes	No
2259	Placebo	No	No	Yes	Yes	Yes	Yes
2260	Placebo	No	No	No	No	No	No
2261	Active	No	No	No	No	No	No
2262	Active	Yes	Yes	Yes	Yes	Yes	Yes
2263	Placebo	No	No	No	No	No	No
2264	Active	No	No	No	No	No	No
2265	Active	No	No	No	No	No	No
2266	Active	No	No	No	No	No	No
2267	Active	No	No	No	No	No	No
2268	Placebo	No	No	No	No	No	No
2269	Placebo	No	No	No	No	No	No
2270	Placebo	Yes	Yes	Yes	Yes	Yes	Yes
2271	Placebo	No	No	No	No	No	No
2272	Placebo	No	No	No	No	No	No
2273	Active	No	No	No	No	No	No
2274	Placebo	No	No	No	No	No	No
2275	Active	Yes	Yes	Yes	Yes	Yes	Yes
2276	Active	No	No	No	No	No	No
2277	Active	Yes	Yes	Yes	Yes	Yes	Yes
2278	Active	No	No	No	No	No	No
2279	Placebo	No	No	No	No	No	No
2280	Placebo	No	No	No	No	No	No
2281	Active	No	No	No	No	No	No
2282	Placebo	No	No	No	No	No	No
2283	Placebo	No	No	No	No	No	No
2284	Active	No	No	No	No	No	No
2285	Active	No	No	No	No	No	No
2286	Placebo	No	No	No	No	No	No
2287	Active	No	No	No	No	No	No
2288	Placebo	No	No	No	No	No	No
2289	Active	No	No	No	No	No	No
2290	Placebo	No	No	No	No	No	No
2291	Active	No	No	No	No	No	No

**CONFIDENTIAL**

**Listing 10: Outcome**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
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A meta-analysis of results from two randomized clinical trials

**(Serbia)**

Subject ID	Group	Primary: Smoking cessation 25-48 weeks	Smoke-free week 24	Smoke-free week 36	Smoke-free week 48	Cessation weeks 45-48	Cessation weeks 37-48
2292	Placebo	No	No	No	No	No	No
2293	Placebo	No	No	No	No	No	No
2294	Active	No	No	No	No	No	No
2295	Active	Yes	Yes	Yes	Yes	Yes	Yes
2296	Active	Yes	Yes	Yes	Yes	Yes	Yes
2297	Placebo	No	No	No	No	No	No
2298	Placebo	No	No	No	No	No	No
2299	Active	No	No	No	No	No	No
2300	Placebo	No	No	No	No	No	No
2301	Active	No	No	No	No	No	No
2302	Placebo	No	No	No	No	No	No
2303	Active	No	No	No	No	No	No
2304	Placebo	No	No	No	No	No	No
2305	Placebo	Yes	Yes	Yes	Yes	Yes	Yes
2306	Active	No	No	No	No	No	No
3001	Placebo	No	No	No	No	No	No
3002	Placebo	No	No	No	No	No	No
3003	Active	No	No	No	No	No	No
3004	Active	No	No	No	Yes	No	No
3006	Placebo	No	No	No	No	No	No
3007	Active	No	No	No	Yes	Yes	No
3008	Active	No	No	No	No	No	No
3009	Placebo	No	No	No	No	No	No
3010	Placebo	No	No	No	No	No	No
3011	Active	No	No	No	Yes	Yes	No
3012	Placebo	No	No	No	No	No	No
3013	Active	No	No	No	Yes	Yes	No
3014	Active	No	No	No	No	No	No
3015	Active	No	No	No	No	No	No
3016	Placebo	No	No	No	No	No	No
3017	Placebo	No	No	No	No	No	No
3018	Placebo	No	No	No	No	No	No
3019	Active	No	No	No	No	No	No
3020	Placebo	No	No	No	No	No	No
3021	Active	No	No	No	No	No	No
3022	Placebo	No	No	No	No	No	No
3023	Active	No	No	No	No	No	No
3024	Placebo	No	No	No	No	No	No
3025	Placebo	No	No	No	No	No	No
3026	Placebo	No	No	No	No	No	No
3027	Placebo	No	No	No	No	No	No
3028	Active	No	No	No	No	No	No
3029	Active	No	No	No	No	No	No
3030	Active	No	No	No	No	No	No
3031	Active	No	No	No	No	No	No
3032	Active	No	No	No	No	No	No
3033	Placebo	No	No	No	No	No	No
3034	Active	No	No	No	No	No	No
3035	Placebo	No	No	No	No	No	No
3036	Placebo	No	No	No	No	No	No
3037	Placebo	No	No	No	No	No	No

**CONFIDENTIAL**

**Listing 10: Outcome**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")

on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**(Serbia)**

<b>Subject ID</b>	<b>Group</b>	<b>Primary: Smoking cessation 25-48 weeks</b>	<b>Smoke-free week 24</b>	<b>Smoke-free week 36</b>	<b>Smoke-free week 48</b>	<b>Cessation weeks 45-48</b>	<b>Cessation weeks 37-48</b>
3038	Active	Yes	No	Yes	Yes	Yes	Yes
3039	Placebo	No	No	No	No	No	No
3040	Active	No	No	No	No	No	No
3041	Placebo	No	No	No	No	No	No
3042	Active	No	No	No	No	No	No
3043	Placebo	No	No	No	No	No	No
3044	Active	No	No	No	No	No	No
3045	Active	No	No	No	No	No	No
3046	Placebo	No	No	No	No	No	No
3047	Active	No	No	No	No	No	No
3048	Placebo	No	No	No	No	No	No
3049	Placebo	No	No	No	No	No	No
3050	Active	No	No	No	Yes	No	No

**CONFIDENTIAL**

**Listing 10: Outcome**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")  
on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**(USA)**

Subject ID	Group	Primary: Smoking cessation 6-28 weeks	Smoke-free week 6	Smoke-free week 16	Smoke-free week 28	Cessation weeks 25-28	Cessation weeks 17-28
R1001	Active	No	No	No	No	No	No
R1002	Placebo	No	No	No	No	No	No
R1003	Active	No	No	No	No	No	No
R1004	Placebo	No	No	No	No	No	No
R1005	Active	No	No	No	No	No	No
R1006	Placebo	No	No	No	No	No	No
R1007	Active	No	No	Yes	No	No	No
R1008	Placebo	No	No	No	No	No	No
R1009	Active	No	No	No	No	No	No
R1010	Active	No	No	No	No	No	No
R1011	Placebo	No	No	No	No	No	No
R1012	Placebo	No	No	No	No	No	No
R1013	Placebo	No	No	No	No	No	No
R1014	Placebo	No	No	No	No	No	No
R1015	Active	No	No	No	No	No	No
R1016	Active	No	No	No	No	No	No
R1017	Active	No	No	No	No	No	No
R1018	Placebo	No	No	No	No	No	No
R1019	Active	No	No	No	No	No	No
R1020	Placebo	No	Yes	Yes	No	No	No
R1021	Placebo	No	No	No	No	No	No
R1022	Active	No	No	No	No	No	No
R1023	Placebo	No	No	No	No	No	No
R1024	Active	No	No	No	No	No	No
R1025	Active	Yes	Yes	Yes	Yes	Yes	Yes
R1026	Active	No	No	No	No	No	No
R1027	Placebo	No	No	No	No	No	No
R1028	Placebo	No	No	No	No	No	No
R1029	Active	No	Yes	No	No	No	No
R1030	Placebo	No	Yes	No	No	No	No
R1031	Active	No	No	No	Yes	No	No
R1032	Active	No	Yes	Yes	No	No	No
R1033	Placebo	No	No	No	No	No	No
R1034	Placebo	No	No	No	No	No	No
R1035	Active	No	No	No	No	No	No
R1036	Placebo	No	No	No	No	No	No
R1037	Active	No	No	No	Yes	No	No
R5001	Placebo	No	No	No	No	No	No
R5002	Active	No	No	No	No	No	No
R5003	Placebo	No	No	No	No	No	No
R5004	Active	No	No	No	No	No	No
R5005	Placebo	No	No	No	No	No	No
R5006	Active	No	No	No	No	No	No
R5007	Active	No	No	No	No	No	No
R5008	Placebo	No	No	No	No	No	No
R5009	Placebo	No	No	No	No	No	No
R5010	Active	No	No	No	No	No	No
R5011	Active	Yes	Yes	Yes	Yes	Yes	Yes
R5012	Placebo	No	No	No	No	No	No
R5013	Active	No	No	No	No	No	No
R5014	Placebo	No	No	No	No	No	No

**CONFIDENTIAL**

**Listing 10: Outcome**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")

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**(USA)**

Subject ID	Group	Primary: Smoking cessation 6-28 weeks	Smoke-free week 6	Smoke-free week 16	Smoke-free week 28	Cessation weeks 25-28	Cessation weeks 17-28
R5015	Placebo	No	No	No	No	No	No
R5016	Placebo	No	No	No	No	No	No
R5017	Active	No	No	No	No	No	No
R5018	Active	No	No	No	No	No	No
R5019	Placebo	No	No	No	No	No	No
R5020	Active	No	No	No	No	No	No
R5021	Placebo	No	No	No	No	No	No
R5022	Active	No	No	No	No	No	No
R5023	Active	No	No	No	No	No	No
R5024	Placebo	No	No	No	No	No	No
R5025	Placebo	No	No	No	No	No	No
R5026	Placebo	No	No	No	No	No	No
R5027	Active	No	Yes	Yes	No	No	No
R5028	Active	No	No	No	No	No	No
R3001	Active	No	Yes	Yes	Yes	Yes	Yes
R3002	Placebo	Yes	Yes	Yes	Yes	Yes	Yes
R3003	Active	No	No	Yes	No	No	No
R3004	Placebo	No	No	No	No	No	No
R3005	Placebo	No	No	No	No	No	No
R3006	Active	No	No	Yes	No	No	No
R3007	Placebo	No	Yes	No	No	No	No
R3008	Placebo	No	No	Yes	Yes	Yes	Yes
R3009	Active	No	Yes	No	No	No	No
R3010	Placebo	Yes	Yes	Yes	Yes	Yes	Yes
R3011	Active	No	Yes	No	No	No	No
R3012	Active	No	No	No	No	No	No
R3013	Active	No	No	No	No	No	No
R3014	Placebo	No	No	No	No	No	No
R3015	Placebo	No	No	No	No	No	No
R3016	Active	No	No	No	No	No	No
R3017	Active	No	No	No	No	No	No
R3018	Placebo	No	Yes	No	No	No	No
R3019	Placebo	No	No	No	No	No	No
R3020	Active	No	Yes	No	Yes	Yes	Yes
R3021	Active	No	No	No	No	No	No
R3022	Placebo	No	No	No	No	No	No
R3023	Placebo	No	No	No	No	No	No
R3024	Active	No	No	No	No	No	No
R3025	Placebo	No	No	No	No	No	No
R3026	Active	No	No	Yes	Yes	Yes	Yes
R3027	Active	No	No	No	No	No	No
R3028	Placebo	No	No	No	No	No	No
R3029	Placebo	No	No	No	No	No	No
R3030	Active	No	No	No	No	No	No
R3031	Active	No	No	No	No	No	No
R3032	Placebo	No	No	No	No	No	No
R2001	Active	No	No	No	No	No	No
R2002	Active	No	Yes	No	Yes	Yes	Yes
R2003	Active	No	Yes	Yes	No	No	No
R2004	Placebo	No	No	No	No	No	No
R2005	Placebo	No	Yes	Yes	Yes	Yes	Yes

**CONFIDENTIAL**

**Listing 10: Outcome**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")

on the Quit Rate among Cigarette Smokers who wish to stop smoking.

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**(USA)**

Subject ID	Group	Primary: Smoking cessation 6-28 weeks	Smoke-free week 6	Smoke-free week 16	Smoke-free week 28	Cessation weeks 25-28	Cessation weeks 17-28
R2006	Placebo	No	No	No	No	No	No
R2007	Placebo	No	No	No	No	No	No
R2008	Active	No	No	No	No	No	No
R2009	Placebo	No	No	No	Yes	Yes	Yes
R2010	Active	No	No	No	No	No	No
R2011	Placebo	No	No	No	No	No	No
R2012	Active	No	No	No	No	No	No
R2013	Active	No	No	No	No	No	No
R2014	Placebo	No	No	No	No	No	No
R2015	Active	No	No	No	No	No	No
R2016	Placebo	No	No	No	No	No	No
R2017	Active	No	Yes	No	No	No	No
R2018	Placebo	No	No	No	No	No	No
R2019	Placebo	No	No	No	No	No	No
R2020	Active	No	No	No	No	No	No
R2021	Active	No	No	Yes	No	No	No
R2022	Placebo	No	No	No	No	No	No
R2023	Placebo	No	No	Yes	No	No	No
R2024	Active	No	Yes	No	No	No	No
R2025	Active	No	No	No	No	No	No
R2026	Active	No	No	No	No	No	No
R2027	Active	No	No	No	No	No	No
R2028	Placebo	No	No	No	No	No	No
R2029	Placebo	No	No	No	No	No	No
R2030	Placebo	No	No	No	No	No	No
R2031	Placebo	No	No	Yes	Yes	Yes	Yes
R2032	Active	No	Yes	No	No	No	No
R4001	Placebo	No	No	No	No	No	No
R4002	Active	No	Yes	No	Yes	Yes	Yes
R4003	Placebo	No	No	No	No	No	No
R4004	Active	No	No	No	No	No	No
R4005	Active	No	No	No	No	No	No
R4006	Placebo	No	No	No	No	No	No
R4007	Active	No	No	No	No	No	No
R4008	Active	No	No	No	No	No	No
R4009	Placebo	No	No	No	No	No	No
R4010	Placebo	No	No	No	No	No	No
R4011	Placebo	No	No	No	No	No	No
R4012	Active	No	Yes	Yes	No	No	No
R4013	Active	No	No	No	No	No	No
R4014	Placebo	No	No	No	No	No	No
R4015	Placebo	No	No	No	No	No	No
R4016	Active	No	No	No	No	No	No
R4017	Active	No	No	No	No	No	No
R4018	Placebo	No	No	No	No	No	No
R4019	Placebo	No	Yes	No	No	No	No
R4020	Active	No	Yes	Yes	No	No	No
R4021	Placebo	No	No	No	No	No	No
R4022	Active	No	No	No	No	No	No
R4023	Placebo	No	Yes	Yes	No	No	No
R4024	Active	No	No	No	No	No	No

**CONFIDENTIAL**

**Listing 10: Outcome**

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**(USA)**

Subject ID	Group	Primary: Smoking cessation 6-28 weeks	Smoke-free week 6	Smoke-free week 16	Smoke-free week 28	Cessation weeks 25-28	Cessation weeks 17-28
R4025	Active	No	No	No	No	No	No
R4026	Placebo	No	No	No	No	No	No
R4027	Active	No	Yes	Yes	No	No	No
R4028	Active	No	No	No	No	No	No
R4029	Placebo	No	Yes	No	No	No	No
R4030	Placebo	No	No	No	No	No	No
R4031	Placebo	No	No	No	No	No	No
R4032	Placebo	No	No	Yes	No	No	No
R4033	Active	No	No	No	Yes	Yes	Yes
R4034	Active	No	No	No	No	No	No
R4035	Active	No	No	No	No	No	No
R4036	Placebo	No	Yes	No	No	No	No
R4037	Placebo	No	No	No	No	No	No
R4038	Placebo	No	No	No	No	No	No
R4039	Active	No	No	No	No	No	No
R4040	Active	No	Yes	Yes	Yes	Yes	Yes
R4041	Placebo	No	No	No	No	No	No
R4042	Active	No	No	No	No	No	No
R4043	Active	No	No	No	No	No	No
R4044	Active	No	No	No	No	No	No
R4045	Placebo	No	No	No	No	No	No
R4046	Placebo	No	No	No	No	No	No
R4047	Placebo	No	No	No	No	No	No
R4048	Active	No	No	No	No	No	No
R4049	Active	No	No	No	No	No	No
R4050	Placebo	No	No	No	No	No	No
R4051	Active	No	No	No	No	No	No
R4052	Placebo	No	No	No	No	No	No
R4053	Active	No	No	No	No	No	No
R4054	Placebo	No	No	No	No	No	No
R4055	Active	No	No	No	No	No	No
R4056	Active	No	No	No	No	No	No
R4057	Active	No	No	No	No	No	No
R4058	Placebo	No	No	No	No	No	No
R4059	Placebo	No	No	No	Yes	Yes	No
R4060	Placebo	No	No	No	No	No	No
R4061	Active	No	No	No	No	No	No
R4062	Placebo	No	No	No	No	No	No
R4063	Active	No	No	Yes	No	No	No
R4064	Placebo	No	No	No	No	No	No
R4065	Active	No	No	No	No	No	No
R4066	Placebo	No	No	No	No	No	No
R4067	Placebo	No	No	No	No	No	No
R4068	Active	No	No	No	No	No	No
R4069	Active	No	No	No	No	No	No
R4070	Placebo	No	No	No	No	No	No
R4071	Active	Yes	Yes	Yes	Yes	Yes	Yes
R4072	Placebo	No	No	No	No	No	No
R4073	Active	No	No	No	No	No	No
R4074	Placebo	No	No	No	No	No	No
R4075	Active	No	No	No	No	No	No

**CONFIDENTIAL**

**Listing 10: Outcome**

Study: SM 11-01 Effect of a Traditional Swedish Smokeless Tobacco Product ("SNUS")

on the Quit Rate among Cigarette Smokers who wish to stop smoking.

A meta-analysis of results from two randomized clinical trials

**(USA)**

Subject ID	Group	Primary: Smoking cessation 6-28 weeks	Smoke-free week 6	Smoke-free week 16	Smoke-free week 28	Cessation weeks 25-28	Cessation weeks 17-28
R4076	Placebo	No	No	No	No	No	No
R4077	Active	No	No	No	No	No	No
R4078	Placebo	No	No	No	No	No	No
R4079	Placebo	No	No	No	No	No	No
R4080	Active	No	No	No	No	No	No
R4081	Active	No	No	No	No	No	No
R4082	Placebo	No	No	No	No	No	No
R4083	Active	No	No	No	No	No	No
R4084	Placebo	No	No	No	No	No	No
R4085	Active	No	No	No	No	No	No
R4086	Active	No	No	No	No	No	No
R4087	Placebo	No	No	No	No	No	No
R4088	Placebo	No	No	No	No	No	No
R4089	Placebo	No	No	No	No	No	No
R4090	Active	No	Yes	Yes	Yes	Yes	No
R4091	Active	No	No	Yes	No	No	No
R4092	Active	No	No	No	No	No	No
R4093	Placebo	No	No	No	No	No	No
R4094	Placebo	No	No	No	No	No	No
R4095	Active	No	No	No	No	No	No
R4096	Placebo	No	No	No	No	No	No
R4097	Active	No	No	No	No	No	No
R4098	Placebo	No	No	No	No	No	No
R4099	Active	No	No	Yes	Yes	No	No
R4100	Active	Yes	Yes	Yes	Yes	Yes	Yes
R4101	Placebo	No	No	No	No	No	No
R4102	Placebo	No	No	Yes	No	No	No
R4103	Placebo	No	No	No	No	No	No
R4104	Placebo	No	No	No	No	No	No
R4105	Active	Yes	Yes	Yes	Yes	Yes	Yes
R4106	Active	No	No	No	No	No	No
R4107	Active	No	No	No	No	No	No
R4108	Placebo	No	No	No	No	No	No
R4109	Placebo	No	No	No	No	No	No
R4110	Active	No	No	No	No	No	No
R4111	Placebo	No	No	No	No	No	No
R4112	Active	No	No	No	No	No	No
R4113	Active	No	No	No	No	No	No
R4114	Placebo	No	No	No	Yes	No	No
R4115	Active	No	No	No	No	No	No
R4116	Placebo	No	No	No	Yes	No	No
R4117	Active	No	No	No	No	No	No
R4118	Placebo	No	No	No	No	No	No
R4119	Placebo	No	No	No	No	No	No
R4120	Active	No	No	No	No	No	No
R4121	Placebo	No	No	No	No	No	No